Medical Product Quality Report – COVID-19 Issues

Issue 4. September 2020

The document has been produced by the Medicine Quality Research Group, Centre of Tropical Medicine & Global Health, Nuffield Department of Medicine, University of Oxford







This report was prepared by Kerlijn Van Assche, Céline Caillet and Paul Newton of the Medicine Quality Research Group, that is part of the MORU Tropical Health Network and the Infectious Diseases Data Observatory (IDDO), Centre for Tropical Medicine & Global Health, Nuffield Department of Medicine, University of Oxford, UK.

The Globe system was developed by Clark Freifeld (HealthMap, Boston Children's Hospital, North Eastern University) and Andrew Payne (IDDO), Alberto Olliaro (IDDO) and Gareth Blower (ex-IDDO) with curation of the English reports by Konnie Bellingham and Ngan Thi Do, linked to the Lao-Oxford-Mahosot Hospital-Wellcome Trust Research Unit (LOMWRU), Microbiology Laboratory, Mahosot Hospital, Vientiane, Lao PDR.

This document is open access but we would be grateful if you could cite it as: Medicine Quality Research Group, University of Oxford. Medical Product Quality Report – COVID-19 Issues. Issue 4, September 2020.

The work is kindly supported by the Bill&Melinda Gates Foundation, the University of Oxford and the Wellcome Trust.

October 2020

Contents

1.	Sui	ımmary of findings	4
2.	Intr	roduction	4
3.	Sci	cientific literature	6
3	3.1.	General	6
3	3.2.	Seizures/Surveys/Case Reports/Reviews	. 10
4.	Inte	ernational organisations	. 11
5.	Mis	scellaneous	. 12
6.	Lay	y literature	. 13
6	5.1	Disclaimer & Notes	. 13
6	5.2	Articles on SF medical products for COVID-19 – main characteristics	. 14
6	5.3	Vaccines	. 16
6	5.4	COVID-19 diagnostics	. 17
6	5.5	Personal protective equipment including sanitizers	. 17
	6.5	5.1 Personal Protective Equipment	. 17
	6.5	5.2 Sanitizers and disinfectant	. 19
6	6.6	COVID-19 medicines	. 20
7.	Anı	nnexes	. 21
7	'.1	Vaccines	
7	.2	COVID-19 diagnostics	
7	'.3	Personal Protective Equipment including sanitizers	
7	'.4	COVID-19 medicines	

1. Summary of findings

The COVID-19 pandemic does not show signs of abating anytime soon. It continues to be a significant market force not only for good quality but more worryingly for substandard and falsified (SF) medical products. Reports on SF COVID-19 supplies range from personal protective equipment and diagnostic tests to vaccines and medicines.

During the month of September substandard remdesivir and falsified COVID-19 vaccines were reported in India. In the United States the Do-Not-Use-List of hand sanitizers kept on growing, albeit at a slower rate compared to the previous months. SF hand sanitizers were reported in Nepal and diverse other countries. The August issue of the medical product quality report reported problems of SF masks in Taiwan and in September additional articles reported on issues of falsified masks with forged labels in Taiwan. Other worrying phenomena are reflected by alerts on used medical gloves and masks that are repacked and sold. The articles discussed in the medical product quality reports are early warnings of potential problems with COVID-19 supplies. For all these products vigilance is needed considering the relentless risk of substandard or falsified versions.

2. Introduction

During the COVID-19 pandemic, the demand for COVID-19 related medical supplies has inevitably ballooned with an increased demand for personal protective equipment (PPE), diagnostics and preventive & curative pharmaceuticals. The high demand and related shortages of genuine products contributes to an increased global risk of substandard and falsified (SF) medical products, for COVID-19 and for many other essential medicines. The media have been reporting diverse examples of SF products flooding the market.

This report aims to collate information and reports in the public domain on the quality of medicinal products that are currently in use, or that are being trialled for COVID-19's prevention or treatment. We also include reports on key subjects such as access, affordability or off label use for COVID-19 if they mention concern of the quality of the products. We do not aim to include discussion of the multiple fraudulent claims and quackery.

We use the terminology for different types of poor quality medical products as defined by the World Health Organisation (WHO, 2017)¹:

⁻

¹Source: World Health Organisation. Appendix 3 WHO MEMBER STATE MECHANISM ON SUBSTANDARD/SPURIOUS/FALSELY-LABELLED/FALSIFIED/COUNTERFEIT (SSFFC) MEDICAL PRODUCTS WORKING DEFINITIONS. In: Seventieth World Health Assembly.; 2017. Accessed August 14, 2020. https://www.who.int/medicines/regulation/ssffc/A70_23-en1.pdf?ua=1

Substandard medical products

Also called "out of specification", these are authorized medical products that fail to meet either their quality standards or their specifications, or both.

Unregistered/unlicensed medical products

Medical products that have not undergone evaluation and/or approval by the national or regional regulatory authority for the market in which they are marketed/distributed or used, subject to permitted conditions under national or regional regulation and legislation.

Falsified medical products

Medical products that deliberately/fraudulently misrepresent their identity, composition or source.

We emphasise the difference between the use of the terms 'falsified' and 'counterfeit' medical products. 'Falsified' is a broad term including all the various types of deliberate misrepresentation of a medical product from a public health perspective. The term 'counterfeit' is specifically linked to intellectual property rights, 'trademark counterfeit goods'² and 'pirated copyright goods'³ as used in the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement.

The reports presented were mostly extracted from the Medicines Quality Monitoring Globe (the MQM Globe is accessible on the IDDO website), a system that scrapes online newspapers (referenced in Google News) for early warnings of substandard and falsified medical products. In addition, alerts and reports by national and international organisations are included when captured by the members of the team or shared by colleagues. This report also includes scientific literature and policy documents related to COVID-19 medical products quality identified by manual searches in Pubmed and Google Scholar. These will be displayed on the Medicine Quality COVID-19 Surveyor to be released in the coming months. We also include preprint of articles. Please note that preprints should be viewed with additional caution as they have not been peer-reviewed. They should not be relied on to guide clinical practice or health-related behaviour and should not be reported in news media as established information.

²Trademark counterfeit goods: any goods, including packaging, bearing without authorization a trademark which is identical to the trademark validly registered in respect of such goods, or which cannot be distinguished in its essential aspects from such a trademark, and which thereby infringes the rights of the owner of the trademark in question under the law of the country of importation.

Source: World Trade Organization. Part III — Enforcement of Intellectual Property Rights. Accessed August 14, 2020. https://www.wto.org/english/docs_e/legal_e/27-trips_05_e.htm#fnt-14

³ Pirated copyright goods: any goods that are copies made without the consent of the right holder or person duly authorized by the right holder in the country of production, and which are made directly or indirectly from an article where the making of that copy would have constituted an infringement of a copyright or a related right under the law of the country of importation.

Source: World Trade Organization. Part III — Enforcement of Intellectual Property Rights. Accessed August 14, 2020. https://www.wto.org/english/docs_e/legal_e/27-trips_05_e.htm#fnt-14

⁴Infectious Diseases Data Observatory. Medicine Quality Monitoring Globe. Web Page. Published 2020. Accessed October 16, 2020. https://www.iddo.org/medicine-quality-monitoring-globe

Please note the caveats for the lay literature (<u>MQM Globe disclaimer and caveats are accessible on the IDDO website</u>⁵); we include abstracts and extracts from articles that are subject to a take down policy. If we are contacted by a potential rights-holder who objects to the presence of material, we will remove the material in question from the report and Globe until we have been able to assess the case. Where material is removed for valid reasons of copyright, its removal will be considered as lasting until copyright in the material expires, or until the rights-holder agrees that the material can be reinstated.

This fourth issue of the monthly report 'Medical Product Quality Report – COVID-19 Issues' covers information published during the month of September. The previous issues covered publications from January 1st to August 31th 2020 and are available on the IDDO website⁶. We also include publications and reports published prior to August 2020 that were missed in the previous issues of the report. We are developing a system for scraping regulatory authority and international organisation websites for alerts. Any remarks or additions to content are greatly appreciated (please write to medicinequality@iddo.org).

3. Scientific literature

3.1. General

Aseffa A, Lulseged S, Makonnen E. **Mitigating the impact of COVID-19 on pharmacovigilance**. *Ethiop Med J.* 2020;58(4). doi:10.1007/s40264-020-00965

Extract of the editorial. « Regulatory systems need to rise up to the challenges posed by COVID-19 to ensure that pharmacovigilance plays its essential role in the COVID-19 response. In Ethiopia, where the COVID 19 pandemic is on the rise, it is necessary to prevent public health damage from this complex pandemic as early as possible. Pharmacovigilance should be one of the priority interventions to this end. It is important that regulatory bodies ensure manufacturers and importers fulfil the required documentations and put in place efficient authorization processes to meet urgent public health needs, while protecting the public from unsafe and poor-quality medical products related to the diagnosis and prevention of COVID-19. The directive recently issued by the Ethiopian Food and Drug Authority (EFDA) (9), which provides directions for COVID-19 medical products conditional approval and import permit authorization is a useful step in the country's effort to guide and monitor the national response to the pandemic. Further measures need to be taken to strengthen pharmacovigilance in the broader sense, while keeping efficiency in perspective. »

Belayneh A. Off-Label Use of Chloroquine and Hydroxychloroquine for COVID-19 Treatment in Africa Against WHO Recommendation. Res Rep Trop Med. 2020; Volume 11:61-72. doi:10.2147/rrtm.s269936.

Abstract. « COVID-19 is continuing as a big challenge for the globe and several types of research are continued to find safe and effective treatment and preventive options. Although there is a lack

⁵Infectious Diseases Data Observatory. Medicine Quality Monitoring Globe disclaimer and caveats. Web Page. Published 2020. Accessed October 19, 2020. https://www.iddo.org/medicine-quality-monitoring-globe-disclaimer-and-caveats

⁶Infectious Diseases Data Observatory. Medical Product Quality Reports. News. Published 2020. Accessed October 10, 2020. https://www.iddo.org/mq/research/medical-product-quality-report

of conclusive evidence of their benefit, there is worldwide controversy to use anti-malarial drugs, hydroxychloroquine and chloroquine, for the treatment of COVID-19. FDA issued an emergency use authorization to the use of these drugs for the treatment of COVID-19. On the contrary to the FDA, the European Medicines Agency has warned against the widespread use of these drugs to treat COVID-19. Finally, the WHO declared that clinical trials on these drugs are halted after the devastating findings of the study published in the medical journal called The Lancet. Against this fact, there are several rumors about the irresponsible use of these drugs in Africa for the treatment of COVID19. This work aimed to review the off-label use of these drugs for the treatment of COVID19 in African countries against WHO recommendation. Data on the use of these drugs for the treatment of COVID-19 in African countries were searched from credible sources including Scopus, PubMed, Hindawi, Google Scholar, and from local and international media. The study showed that many African countries have already approved at the national level to use these drugs to treat COVID-19 by opposing WHO warnings. In addition to this, falsified and substandard chloroquine products started to emerge in some African countries. The health sectors of the African government should critically compare the risks and benefits before using these drugs. The WHO and African drug regulatory organizations should intervene to stop the off-label use practice of these drugs against the licensed purpose and distribution of falsified and substandard products in the continent. »

Forouzandeh P, O'Dowd K, Pillai SC. Face masks and respirators in the fight against the COVID-19 pandemic: An overview of the standards and testing methods. *Saf Sci.* 2020;133:104995. doi:10.1016/j.ssci.2020.104995.

Abstract. « The COVID-19 outbreak has resulted in a shortage of personal protective equipment (PPE) throughout the world. This shortage has resulted in an increase in production of PPE to meet the demand, and as a result, several substandard equipment has entered the market. With face masks and respirators now beginning to see widespread use throughout the world, the standards and test with which they are required to undertake have become points of interest. The filtration efficiency of the masks is a key testing element that examines its ability to filter particles, bacteria and viruses; this examines the penetration efficiency percentage of each with lower results being preferable. Masks are also subjected to NaCl testing method, which allows a range of particle sizes to be examined and their penetration to be observed. The masks must also show considerable resistance to fluids and flames, to prevent the penetration of liquids and to be non-flammable. Various PPE testing protocols such as biological, chemical, fluid and flame resistances, protective ensemble, facepiece fit testing, NIOSH NaCl method and impact protection have been discussed. In addition, various tests involving bacterial and viral filtration efficiencies are also discussed. Differential pressure is examined to ensure a correct fit of the mask. »

Jefferson M. COVID-19: The Lessons We Should Have Learned from Existing Literature. *Biophys Econ Sustain*. 2020;5(3):3. doi:10.1007/s41247-020-00079-y

Abstract. « The linkages between natural resources and human well-being lie at the heart of biophysical economics. Huge disruptions to human well-being which can occur as a result of the impact of particular natural resources or species are, or should be, an obvious focus of interest for the biophysical economist whose focus is on flows between the natural world and human society. The causes and consequences of such disruptions, such as emanate from pandemics and epidemics, are a clear example of this. There is a need for better understanding of these causes and consequences. As an example, twelve books on epidemics and pandemics are considered here as providing the core for what guidance they might, and should, have provided on the sources, spreaders, and responses to COVID-19. A substantial amount of guidance is given in these and other sources referenced, which if followed would have reduced spread and mortality, but in far too many countries preparedness and speed of responses were inadequate. An effective global network and funding are required, as long advocated, but still not implemented. The economic and resource costs of this failure are huge. »

Kalidoss VK, Bakshi SS. **Has the use of hand sanitiser substituted hand hygiene in the current COVID-19 pandemic?** A perilous path. *J R Coll Physicians Edinb*. 2020;50(3):343-350. doi:10.4997/JRCPE.2020.330

Extract of the text. « There are other issues too, like the availability of substandard sanitisers on the market. This is of particular concern as the FDA recommends 60–95% of ethanol or isopropyl alcohol for a hand sanitiser to be effective, but there are many sanitisers available online which have a much lower concentration or the concentration information is not available. We would like to conclude that although hand sanitisers are a very effective measure of hand hygiene, their blind promotion should be avoided. The public should be educated in hand hygiene measures and should be made aware that hand sanitisers are not a substitute for the age-old, time-tested technique of hand washing with soap and water. Judicious use of standardised hand sanitisers is the need of the hour and we as healthcare workers should take the front line in educating the public about the same. »

Kohler JC, Wright T. **The Urgent Need for Transparent and Accountable Procurement of Medicine and Medical Supplies in Times of COVID-19 Pandemic.** *J Pharm Policy Pract.* 2020;13(1). doi:10.1186/s40545-020-00256-w

Abstract. « The COVID-19 pandemic has unleashed unprecedented and complex public policy issues. One that has emerged as a challenge for many countries globally is how to ensure the efficient and effective procurement of quality medical supplies. Existing corruption pressures on procurement—everything from undue influence to the outright bribery of public officials—has been amplified by the pandemic, and thus demands commensurate policy responses. We argue that transparency and accountability in procurement are essential to preventing the corruption risks that threaten the health and well-being of populations. »

Mennechet FJD, Dzomo GRT. Coping with COVID-19 in Sub-Saharan Africa: What Might the Future Hold? *Virol Sin.* Published online 2020:1. doi:10.1007/s12250-020-00279-2

Extract of the text. « Despite the enormous and global controversy over the use of hydroxychloroquine that has lasted for months, and against the WHO recommendations, many African countries are still refusing to abandon hydroxychloroquine or chloroquine for the treatment of COVID-19. Since the beginning of the epidemic, people infected with COVID-19 in the Republic of Chad are treated with chloroquine and azithromycin. In addition to the elements that call into question the therapeutic use of this drug for the treatment of COVID-19, there is also the very real threat of self-medication and the risk of the use of counterfeit drugs that are already flooding markets in Africa. »

[Preprint] Novotny T. **Chloroquine and Hydroxychloroquine: how about switching?** *Authorea Prepr.* Published online September 11, 2020. doi:10.22541/AU.159986538.81056460

Abstract. « Early studies suggesting that chloroquine (CQ) and hydroxychloroquine (HCQ) could benefit coronavirus patients brought these old medicines back to the spotlight. This led to an increase in demand and price, turning their counterfeiting a pharmacovigilance issue worldwide. Meanwhile, lack of evidence on effectiveness and safety concerns have reduced their clinical trials in severe COVID-19 cases. Despite the knowledge that CQ and HCQ toxic effects are stereo specific rather than their therapeutic effects, these drugs are available only as racemates. In this context, this work brings a discussion about chiral switching to their eutomers so that CQ and HCQ distomers would become impurities, what may be a viable alternative to test new dose-response curves. Even if it is proven that the use of pure CQ and HCQ enantiomers are useless against COVID-19, chiral switching would certainly improve safety and efficacy in the treatment of many autoimmune inflammatory diseases, benefiting chronic users of these drugs. »

[Preprint] Nyamweya NN, Abuga KO. **Alcohol-Based Hand Sanitizers-A Multidimensional Perspective.** Published online September 15, 2020. doi:10.20944/preprints202009.0337.v1

Abstract. « The global use of alcohol based hand sanitizers (ABHS) as a means of controlling the transmission of infectious disease increased dramatically in 2020 as governments and public health agencies across the world advocated hand hygiene as a preventative measure during the COVID-19 pandemic. Although the performance of these products is most commonly defined as a function of their alcohol concentration, they are multifaceted products in which an interplay of several factors is important in determining efficacy. The hand sanitizer tetrahedron, is a novel concept that considers both ABHS formulation factors and product performance factors from a multi-dimensional perspective. The four faces of the tetrahedron represent input/formulation factors: 1) the type and amount of alcohol, 2) inactive ingredients, 3) the type of formulation/delivery system and 4) manufacturing practices. The four corners of the tetrahedron represent output/product performance factors: 1) efficacy, 2) sensory characteristics, 3) usage, usability and compliance and 4) product safety/adverse effects. All factors are of importance to ensuring the effectiveness and utility of these products. »

Proffitt E. **The dangers of fake PPE.** *BDJ Team.* 2020;7(8):20-21. doi:10.1038/s41407-020-0399-5

Extract from the text. « The COVID-19 pandemic has shone a spotlight on some of the amazing selfless and caring aspects of human nature. However, it has also highlighted some more unsavoury aspects, a key one being the manufacture and supply of fake and non-compliant personal protective equipment (PPE). Unfortunately, it does not come as a great surprise that in these very challenging times when there is unprecedented global demand for face masks and PPE, millions of counterfeit products are appearing on the market, largely on sale from online vendors and linked to resourceful and adaptive criminal gangs.

The British Dental Industry Association (BDIA) has been operating its Counterfeit and Substandard Instruments and Devices Initiative (CSIDI) awareness campaign in the dental press for several years now and is delighted with the significant increase in the dental profession's knowledge and understanding of the dangers of counterfeit and non-compliant dental devices. There is now significantly greater awareness of the issues and dangers associated with fake and non-compliant devices, the implications for users and patients and, very importantly, an understanding of the importance of purchasing from reputable suppliers, such as BDIA members, and being incredibly wary of 'too good to be true' online offers from unfamiliar suppliers.'

White NJ, Watson JA, Hoglund RM, Chan XHS, Cheah PY, Tarning J. **COVID-19** prevention and treatment: A critical analysis of chloroquine and hydroxychloroquine clinical pharmacology. *PLoS Med.* 2020;17(9):e1003252. doi:10.1371/journal.pmed.1003252

Extract of the text. « Diversion. Recommending valuable drugs for unproven indications wastes valuable resources, damages health, and compromises finding effective medicines. People are likely to assume that recommended drugs do work and, in the context of preventive use, will believe they are protected and therefore may not take other necessary precautions or adhere to other public health measures. Taking drugs is easier than complying with public health measures such as physical distancing and wearing protective equipment. In addition, the high demand for these currently unproven drugs has put patients at risk who legitimately need them for treatment for other conditions such as SLE and rheumatoid arthritis. Shortages have already occurred and prices have risen markedly, leaving these vulnerable groups to suffer unnecessarily. It could also encourage unscrupulous manufacturers to make falsified chloroquine and hydroxychloroquine.»

3.2. Seizures/Surveys/Case Reports/Reviews

Mwema FM, Nyika JM. Challenges in facemasks use and potential solutions: The case study of Kenya. *Sci African*. 2020;10:e00563. doi:10.1016/j.sciaf.2020.e00563

Abstract. « The emergence of the novel Coronavirus has forced most governments across the world to enact stringent public laws to curb its transmission among the populations. The requirement to wear a facemask whenever in public places is one of such laws. As such, the demand for such masks has escalated across the world and this predisposition has presented a manufacturing challenge to the developing countries, which have limited capacity to meet the demand for their large populations. In developing countries such as Kenya, the citizens are now required to wear facemasks when in public places such as markets, streets, shopping malls, etc. With limited supply of the proper facemasks in the developing countries, the public is left to improvise them from the available resources. Alternatively, they purchase substandard facemasks from uncertified suppliers and sellers. The purchased masks do not meet the required health standards in most cases. In Kenya, for example, the government has been discouraging citizens from using N95 respirators and instead preserve them for medical practitioners due to their rarity and incapacity to manufacture them. The government has certified several textile industries to produce facemasks for the public from non-woven fabric materials. The challenge with such a move is that there has been an influx of an assortment of facemasks in the Kenyan market and it is not possible for the citizens to identify the safe ones. In this short communication, a brief description of the challenges facing the citizens in terms of access to and quality of face masks in developing countries, with a case study of Kenya is provided. Furthermore, a proposed design solution and a proof of concept of a low-cost and reusable 3D printed facemask for developing economies is herein presented. The adoption of such a design by the governments and manufacturers would solve the challenges of access and quality of the respirators to lower the transmissions of the Coronavirus. »

Additional publications prior to September 2020

Fonseca Jr. F, Brito L, Pimentel MF, Leal L. **Determination of Ethanol in Gel Hand Sanitizers Using Mid and Near Infrared Spectroscopy.** *J Braz Chem Soc.* 2020;31(9):1759-1763. doi:10.21577/0103-5053.20200115

Abstract. « Alcohol-based gel hand sanitizers became very popular during the COVID-19 (coronavirus disease 2019) pandemic. In Brazil, several irregular factories emerged requiring an efficient control by the police and regulatory agencies to guarantee product quality. This problem required a method to determine ethanol content, which led to the development of two methods employing mid and near infrared spectroscopy associated with chemometrics. Partial least squares (PLS) models were built and presented satisfactory results with mean absolute percentage error of prediction and root mean square error of prediction (RMSEP) of 1.12 and 0.76% (m/m), respectively, for mid-infrared (MIR) and 1.83 and 1.18% (m/m) for near-infrared (NIR). The analysis of commercial and seized samples of hand sanitizers showed that only 7 out of 34 samples had an ethanol content of 70% (m/m) or higher. This result reinforces the need for constant vigilance by authorities to ensure that the products have the required specifications. »

Schilling K, Gentner DR, Wilen L, et al. **An accessible method for screening aerosol filtration identifies poor-performing commercial masks and respirators.** *J Expo Sci Environ Epidemiol.* Published online 2020. doi:10.1038/s41370-020-0258-7

Abstract. « Background: The COVID-19 pandemic has presented an acute shortage of regulation-tested masks. Many of the alternatives available to hospitals have not been certified, leaving uncertainty about their ability to properly protect healthcare workers from SARS-CoV-2 transmission.

Objective: For situations where regulatory methods are not accessible, we present experimental methods to evaluate mask filtration and breathability quickly via cost-effective approaches (e.g.,

~\$2000 USD) that could be replicated in communities of need without extensive infrastructure. We demonstrate the need for screening by evaluating an existing diverse inventory of masks/respirators from a local hospital.

Methods: Two experimental approaches are presented to examine both aerosol filtration and flow impedance (i.e., breathability). For one of the approaches ("quick assessment"), screening for appropriate filtration could be performed under 10 min per mask, on average. Mask fit tests were conducted in tandem but are not the focus of this study.

Results: Tests conducted of 47 nonregulation masks reveal variable performance. A number of commercially available masks in hospital inventories perform similarly to N95 masks for aerosol filtration of 0.2 µm and above, but there is a range of masks with relatively lower filtration efficiencies (e.g., <90%) and a subset with poorer filtration (e.g., <70%). All masks functioned acceptably for breathability, and impedance was not correlated with filtration efficiency. »

4. International organisations

Centers for Disease Control and prevention. Yip L, Bixler D, Brooks DE, et al. **Serious Adverse Health Events, Including Death, Associated with Ingesting Alcohol-Based Hand Sanitizers Containing Methanol — Arizona and New Mexico, May–June 2020.** *MMWR Morb Mortal Wkly Rep.* 2020;69(32):1070-1073. doi:10.15585/mmwr.mm6932e1

Summary. « What is already known about this topic? Alcohol-based hand sanitizers should only contain ethanol or isopropanol, but some products imported into the United States have been found to contain methanol.

What is added by this report? From May 1 through June 30, 2020, 15 cases of methanol poisoning were reported in Arizona and New Mexico, associated with swallowing alcohol-based hand sanitizers. Four patients died, and three were discharged with visual impairment.

What are the implications for public health practice? Alcohol-based hand sanitizer products should never be ingested. In patients with compatible signs and symptoms or after having swallowed hand sanitizer, prompt evaluation for methanol poisoning is required. Health departments in all states should coordinate with poison centers to identify cases of methanol poisoning. »

Europol. No safe market for fakes: 21 countries target illegal goods in Europewide sting | Europol. Press Release. Published September 25, 2020. Accessed October 16, 2020. https://www.europol.europa.eu/newsroom/news/no-safe-market-for-fakes-21-countries-target-illegal-goods-in-europe-wide-sting

Extract from the text. « Europe-wide operation Aphrodite has brought together 21 countries* to target counterfeit goods trafficking. The eight-month operation was co-led by the Italian Finance Corps (Guardia di Finanza) and the Irish National Police (An Garda Síochána) with support from Europol. From December 2019 to July 2020, law enforcement authorities tracked online sales of a large variety of counterfeit items, culminating in checks in warehouses, shops and marketplaces in Belgium, Cyprus, Greece, Ireland, Italy, Portugal, Romania and Spain.

Law enforcement find fake COVID-19 medical equipment among the seizures. The operation led to 123 social media accounts and 36 websites selling counterfeit products to be taken down. During the operation, law enforcement authorities seized nearly 28 million illegal and counterfeit goods among which were 800 000 counterfeit items of clothing, sportswear, footwear, personal accessories, IPTV set-top boxes and toys. Ten people were arrested in Greece and 37 others were reported to the judicial authorities in Greece, Italy and Portugal. More than €700 000 was also seized. The COVID-19 outbreak led the involved authorities to adapt the initial scope of the operation to focus on issues triggered by the pandemic. As a result, counterfeit and not compliant medical equipment was also seized, including 27 million medical facemasks, by the Italian Finance Corps (Guarda di Finanza).»

5. Miscellaneous

GS1. Jonasson P, Board E, Clemens R, Van Der Wilden E, Voorspuij J. Sustainable post-COVID-19 supply chain recovery through global data standards: Building a resilient supply chain through product identification and data sharing A contribution to the Policy Hackathon on Model Provisions for Trade in Times of Crisis and Pan. 2020. Accessed October 8, 2020. https://www.unescap.org/sites/default/files/113%20Final-Team%20Patrik%20Jonasson-GS1.pdf

Extract of the text. « Comprehensive product quality and supply chain security requires a multilayer approach that includes prevention, detection, and response strategies and actions. To address the issue of substandard and falsified medical products, regulators, industry stakeholders, representatives from non-governmental organizations, international organizations, and academics came together to create the "APEC Roadmap to Promote Global Medical Product Quality and Supply Chain Security: Supply Chain Security Toolkit"."

Published in August

Aidspan. Boulanger C, Amendah D. Corruption, fraud and disinformation during the Coronavirus disease 2019: heightened vigilance is necessary. 2020 August 26. Accessed October 8, 2020. https://www.aidspan.org/en/c/article/5264

Abstract. International donors, including the Global Fund to Fight AIDS, Tuberculosis and Malaria, promptly made funds available to assist the fight of the COVID-19 pandemic. It is important to assess whether existing mechanisms, including the Global Fund's "three-line defense model," can be used to manage risk in the context of the COVID-19 crisis. Allegations of fraud and corruption are multiplying across countries. Aidspan relies on civil society organizations to help maintain accountability in this COVID-19 pandemic.

6. Lay literature

6.1 Disclaimer & Notes

The information included below is based on the data used to create the Medicine Quality Monitoring Globe⁷ (MQM Globe). It contains publicly available information on the quality of medical products from non-peer-reviewed lay literature. We report the information as it is stated in the articles and can thus be biased towards the authors perspective. It does not necessarily reflect our vision or judgment on the issue. Also, this information usually will not have scientific confirmation. Therefore, the information needs to be interpreted with the greatest caution. We regard the reports as early warnings of potential problems. No or few articles from a region does not imply that the medical product quality there is good, but probably reflects a lack of accessible information. Full disclaimer and caveats can be found at MQM Globe disclaimer and caveats⁸.

The Google News search tool is used to capture data from online news sources. Articles matching the search terms are loaded into a database and curated by trained analysts. Because the Globe system extracts newspaper articles from journals referenced in Google News only, reports not referenced in Google News would not be captured. Please consult the IDDO website for full methodology⁹. On the 20th of March, the search terms were adapted to capture more papers on substandard and falsified (SF) medical supplies for COVID-19.

The news articles discussed in the sections below are available in the Globe-reports, in this report's annexes, or on the online MQM Globe using the report ID (six digits code). The MQM Globe-reports are generated with pre-defined search terms, which enable quick access to reports of (a) COVID diagnostics, (b) Personal protective equipment, (c) COVID medicines, and (d) Ventilators and Positive end-expiratory pressure.

In this report we share articles captured by the MQM Globe that are linked to medical products potentially used in the context of COVID-19 or to active pharmaceutical ingredients (APIs) that are being trialled for COVID-19 treatment and/or prevention. In theory there is a distinction between (a) SF incidents that are due to or increased by the COVID-19 epidemic; and (b) incidents that would have happened in any case. It can be difficult to make the distinction between the two types of incidents and some reports cited below are not directly linked to the treatment of COVID-19. Nevertheless we have included them as crossover risks and to assess the evolution of the alerts on

⁷Infectious Diseases Data Observatory. Medicine Quality Monitoring Globe. Web Page. Published 2020. Accessed October 16, 2020. https://www.iddo.org/medicine-quality-monitoring-globe

⁸ Infectious Diseases Data Observatory. Medicine Quality Monitoring Globe disclaimer and caveats. Web Page. Published 2020. Accessed October 19, 2020. https://www.iddo.org/medicine-quality-monitoring-globe-disclaimer-and-caveats

⁹Infectious Diseases Data Observatory. Medicine Quality Monitoring Globe methodology. Web Page. Published 2020. Accessed October 19, 2020. https://www.iddo.org/medicine-quality-monitoring-globe-methodology

these medical products over time. Although oxycodone is trialled in two studies^{10,11}, we do not include issues related to oxycodone as the system would become swamped by reports on its inappropriate use and cases of pills laced with fentanyl due to its wide occurrence on the black market.

For this report, we only included data that were published in English. For articles in French, Spanish, Mandarin, and Vietnamese; please consult the online MQM Globe. We will continuously work to improve the MQM Globe and plan to add in articles in other languages to this report. Any remarks or additions to content are encouraged (please write to medicinequality@iddo.org).

6.2 Articles on SF medical products for COVID-19 – main characteristics

Since the beginning of the pandemic we have identified 380 relevant articles on quality problems of COVID-19 medical products. For the month of September we report on 53 articles linked to SF COVID-19 supplies alerted through the MQM Globe database (see table 1). Within those articles, 2 alerted on vaccines, 8 on diagnostics, 16 on COVID-19 related treatments and 33 are linked to personal protective equipment (PPE) (see figure 1). Similar to July and August, the MQM Globe did not identify any report linked to ventilation equipment in September.

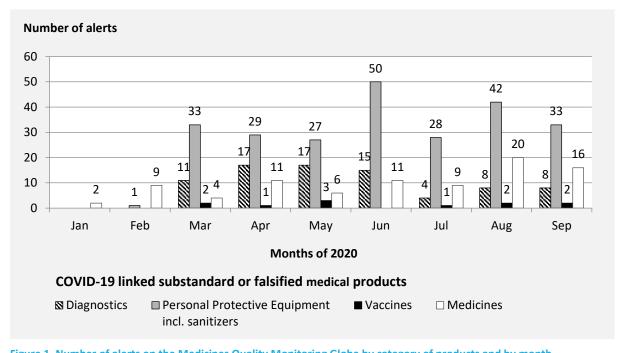


Figure 1. Number of alerts on the Medicines Quality Monitoring Globe by category of products and by month.

ALERTS ARE FOR SUBSTANDARD OR FALSIFIED PRODUCTS LINKED TO COVID-19. As SOME ARTICLES DESCRIBE MORE THAN ONE CATEGORY OF PRODUCTS. THE SUM OF ALERTS PER MONTH MAY EXCEED THE SUM OF ARTICLES PER MONTH REPORTED IN TABLE 1.

-

¹⁰Ghanei M. Safety and Efficacy of Hydroxychloroquine + Favipiravir Drug Regimen in Comparison With Hydroxychloroquine + Kaletra on the Need for Intensive Care Unit Treatment in Patients With COVID-19. Iranian Registry of Clinical Trials. Published April 8, 2020. Accessed October 9, 2020. https://en.irct.ir/trial/46968
¹¹Hashemian SRM. Evaluation the effects of Oxycodone administration on pain control in patients with COVID-19. Iranian Registry of Clinical Trials. Published June 8, 2020. Accessed October 9, 2020. https://en.irct.ir/trial/48534

Table 1. Number of articles on the Medicines Quality Monitoring Globe linked to substandard or falsified COVID-19 supplies by month. As some articles describe more than one category of products, the sum of alerts per month as shown in figures 1 and 2 may exceed the sum of articles per month of table 1.

Month	Number of articles
January	2
February	10
March	49
April	50
May	47
June	64
July	42
August	62
September	53

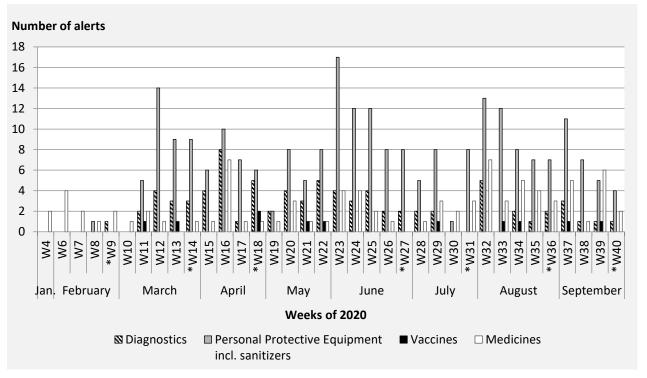


Figure 2. Number of alerts on the Medicines Quality Monitoring Globe by category and by week.

ALERTS ARE FOR SUBSTANDARD OR FALSIFIED PRODUCTS LINKED TO COVID-19. WEEK 4 STARTS ON MONDAY 20TH OF JANUARY 2020 AND WEEK 40 ENDS ON WEDNESDAY 30TH OF SEPTEMBER 2020. WEEKS WITH AN ASTERISK ARE OVERLAPPING 2 MONTHS, EACH TIME THE WEEK IS ATTRIBUTED TO THE EARLIEST MONTH. AS SOME ARTICLES DESCRIBE MORE THAN ONE CATEGORY OF PRODUCTS, THE SUM OF ALERTS PER MONTH MAY EXCEED THE SUM OF ARTICLES PER MONTH REPORTED IN TABLE 1.

Online substandard and falsified products

An abundant presence of COVID-19 related SF products continues to be available online. The articles addressing all types of online COVID-19 products are discussed in this section. One article goes deeper into the sales of online COVID-19 products on the darknet: COVID-19 testing kits, vaccines, hydroxychloroquine pills and used facemasks (report ID 723812). It displays how darknet sellers found a way to make money during the pandemic by diversifying their portfolio. An interviewed darknet

vendor however claims not only to have financial motives for its business but really wants to save lives.

In the August report, we shared the study published by Mackey et al. 2020 on COVID-19 products offered on Twitter and Instagram during the months March to May¹². An article in the lay press picked up on the paper explaining that there are waves of products on offer on social media platforms as demand and supply of these products change in the market (report ID 713833). For example, a first wave of preventive treatments was followed by a second wave of unapproved diagnostics products and PPE. With increased testing capacity the offer of COVID-19 testing kits went down on social media. The growing third wave consists of falsified pharmaceutical treatments.

The United States (US) Food and Drug Administration (FDA) has repeated its warning for consumers to raise awareness for (online) misleading COVID-19 products (report ID 722073). They have seen unauthorised COVID-19 testing kits and medicines, and they warn of other fraudulent products such as medical devices and vaccines. The article mentions several actions taken by the FDA to protect consumers from SF products: removing misleading products from the physical and online market, actively monitoring the sales (of online platforms), issuing warning letters to companies (examples of warning letters are report ID 723098 and 723165), increasing enforcement at ports of entry, and performing seizures (examples of seizures at ports of entry are report ID 727707 and 732067).

6.3 Vaccines

Dozens of coronavirus vaccines are sold online according to an article in the USA (report ID 723812). In India several media reported on a falsified COVID-19 vaccine in Odisha state (report ID 742841). Authorities raided a manufacturing unit and seized vials labelled as "COVID-19 vaccine". Allegedly the product had not been sold yet. The owner was arrested but refused to reveal the composition of the falsified product, and further inspection is continuing. Interestingly our system also highlighted an article discussing the introduction of blockchain technology in Telangana State to combat against substandard and falsified COVID-19 vaccines¹³. UNICEF uses blockchain technology, Vaccine Ledger, that would provide information on the product while moving through the supply chain.

-

¹²Mackey TK, Li J, Purushothaman V, et al. Big Data, Natural Language Processing, and Deep Learning to Detect and Characterize Illicit COVID-19 Product Sales: Infoveillance Study on Twitter and Instagram. JMIR Public Heal Surveill. 2020;6(3):e20794. doi:10.2196/20794

¹³Sur A. Telangana to combat black marketing of COVID-19 vaccine via blockchain. The New Indian Express. Published September 28, 2020. Accessed October 15, 2020. https://www.newindianexpress.com/states/telangana/2020/sep/28/telanganato-combat-black-marketing-of-COVID-19-vaccine-via-blockchain-2202846.html

6.4 COVID-19 diagnostics

The police arrested the head of a manufacturing unit in the Indian state of Uttar Pradesh for producing falsified COVID-19 antibodies rapid test kits with forged labels (report ID 746390). Poor quality tests are used at the parliament according to one of the members of the Indian Parliament, Lok Sabha (report ID 729474). There is no indication in the article if the tests were falsified or substandard.

In the USA the FBI warned for falsified COVID-19 test kits sold door-to-door, via telemarketing calls and via social media platforms (report ID 719163). The FDA confirmed that unauthorized COVID-19 testing kits are sold online (report ID 722073). A darknet dealer allegedly sold IgM/IgG Rapid Tests to medical centres in Italy and the USA after buying them directly from manufacturers in Germany and Korea (report ID 723812). He also claims that some governments are buying COVID-19 testing kits on the darknet. Customs in the USA reported seizures of COVID-19 test cards, rapid kits and detection kits (report ID 740485).

Following online advertisement Kenyan authorities tracked down a shop that was allegedly selling falsified COVID-19 test kits (report ID 713707).

6.5 Personal protective equipment including sanitizers

Thirty-three articles are linked to SF equipment used in the protection against SARS-COV-2. Twenty articles report exclusively on SF personal protective equipment (PPE), out of which the majority discuss masks and respirators and two discuss gloves. Nine articles reported on problems with SF hand sanitizers. Other articles discuss a combination of products.

6.5.1 Personal Protective Equipment

Falsified nitrile gloves were sold to front-line workers in the USA (report ID 728784). The police raided an unlicensed factory and seized 900,000 pairs of 'medical' gloves in Thailand (report ID 723710). The gloves did not meet the national standards and allegedly it were used gloves repacked in boxes to make them look as new.

SF masks in Taiwan

In August problems of SF masks in Taiwan came to light. The Taiwanese authorities tightened inspections on import and sales to track falsified masks. In September several articles pointed on a growing number of SF mask issues. Problems occurred at suppliers that are part of the government's mask rationing system and at entities that are not in the national team of suppliers.

Chinese masks labelled with the wrong origin: The Ministry of Economic Affairs tracked down two Taiwanese mask producing companies which were selling non-medical grade Chinese masks as "Made in Taiwan". The first company was importing and repacking over 3 million Chinese masks as 'Carry Mask' to repurpose them for the Taiwan mask rationing system. The fraud was uncovered after complaints of pharmacies of labels in simplified Chinese script (report ID 714826). The second company was Haw Ping Co which allegedly imported over 7 million masks from China

selling them as "Made in Taiwan" (report ID 722442).

Falsified masks of unknown origin: Over 600,000 non-medical grade masks were packed to look like a genuine product from the official manufacturer Hung Wei Medical Consumable Co. of Taiwan (report ID 719567). The source of the masks is unknown. The owner of the company has been detained for allegedly supplying pharmacies with the falsified product.

Production of falsified masks: A clandestine Taiwanese mask factory was producing masks falsely labelled as manufactured by Taiwan Pro-Level Papers International Co and falsely using the companies medical device license number on the packaging (report ID 723919). During a raid 400,000 masks were seized together with raw materials to potentially produce over an additional 2.5 million masks. A suspect was detained for allegedly selling 750,000 falsified masks to pharmacies across the country.

Selling unapproved masks: A shop of the drugstore chain Great Tree Pharmacy has allegedly been selling masks made in Philippines as masks of the official Taiwanese mask rationing system (report ID 729679). A client noticed the masks were not "Made in Taiwan", but were labelled as "Med Tecs" from the Philippines. Great Tree Pharmacy allegedly has bought the masks through qualified channels and claims it had no intention to act outside the frame of the mask rationing system.

Issues linked to importation

In the USA, the Customs and Border Protection (CBP) seized falsified N95 respirators: 20,400 coming from Hong Kong (report ID 732067) and 500,000 coming from China (report ID 727707). Analysis revealed that 10% of the tested respirators coming from China had a filter efficiency below 95%. Custom officers in Japan seized falsified masks of a Japanese brand (report ID 725140). In the Philippines the Department of Trade and Industry was urged to track down sellers of imported substandard masks (report ID 719408). Some imported masks allegedly do not comply with the Philippine standards. Another problem at the Philippine border involves a shipment that was coming from Singapore declared as PPE, which turned out to be undocumented medicines and ointments (report ID 737299).

Sourcing difficulties for governments and contractors

Articles continue to report on governments facing difficulties with the purchase of masks. In Bangladesh over 20,000 falsified N95 respirators were supplied to 10 health care institutes (report ID 746401). Six officials of the Central Medical Stores Depot and the supplier were held responsible. In India, in Tamil Nadu state, officials received substandard masks from a contractor (report ID 715991). Out of 1.2 million masks almost 600,000 were rejected following quality checks. In the USA, the government contractor MJL enterprise sued Eco Lighting USA Limited Liability Company (report ID 712513). Allegedly Eco Lighting supplied falsified N95 and KN95 respirators to MJL together with certificates falsely claiming the masks were FDA certified.

In the USA the National Institute for Occupational Safety and Health (NIOSH) shared a list of suspected brands of falsified N95 respirators, together with an update on their guidance with regards to falsified respirators and misrepresentation of NIOSH-

approvals (report ID 712648). The article encourages "Contractors should carefully consider where they buy their masks".

Miscellaneous

In South Africa four companies were charged and several companies investigated for supplying substandard PPE (report ID 716864). In Bangladesh an article reports on the lack of guidelines and monitoring of the quality of PPE in Bangladesh, creating a vacuum for fraudsters to sell 'substandard' products (report ID 743276). The ECRI, a non-profit patient safety organization, tested the quality of 200 KN95 masks from 15 different manufacturers imported from China into the US (report ID 761005). Result show that 70% did not meet the filtration standards of KN95 masks.

In Morocco a man was arrested for repacking and selling falsified masks and 121,600 masks were seized (report ID 736630). In India falsified N95 respirators are present in the market and clandestine manufacturers have been taken to court (report ID 748680). An article reported on operation Aphrodite, an operation supported by Europol targeting counterfeit goods trafficking that ran from December 2019 to July 2020 (report ID 745185). Due to the pandemic the initial scope was adapted which led, amongst others, to seizures of 27 million falsified and unregistered medical facemasks by the Italian Finance Corps. It is the first alert the MQM-Globe database holds on SF products in Italy.

6.5.2 Sanitizers and disinfectant

The MQM Globe alerted on the first articles on SF hand sanitizers in Nepal. Around 45 percent of hand sanitizers sold on the local market are substandard or falsified according to results published by the Nepal Academy of Science and Technology (report ID 730915). In September the Nepal Department of Drug Administration banned hand sanitizers from nine companies due to high amounts of methanol (report ID 725135, 730915). At least seven of the companies were based in Nepal and one in India.

The Indian Central Drugs Standard Control Organization (CDSCO) released the monthly routine quality tests on a range of pharmaceutical products results for August. Eight hand sanitizers were declared as "Not of Standard Quality", after failing the tests for the identification of isopropyl alcohol and/or assay of ethyl/isopropyl alcohol (report ID 727310).

During the month of September the US FDA continued to add hand sanitizers to their Do-Not-Use-List¹⁴ (report ID 724196, 732787, 745249). Several retail chains, unknowingly selling methanol containing products, launched recalls. Although more than twenty products were added, the growth of the list slowed down compared to the previous months June, July and August. The vast majority of products on the FDA's Do-Not-Use-list are allegedly coming from Mexico. An article in the Mexico News Daily expressed the concern that several products that are banned in the USA, are still

-

¹⁴United States Food and Drug Administration. FDA updates on hand sanitizers consumers should not use. Drug Safety and Availability. Published June 19, 2020. Accessed October 19, 2020. https://www.fda.gov/drugs/drugsafety-and-availability/fda-updates-hand-sanitizers-consumers-should-not-use

available in Mexico (report ID 723274). For example the company 4E Global, which has 37 hand sanitizers on the Do-Not-Use-list, mentions on its English language website about some products containing methanol. Whereas the Spanish language website does not mention any problem of methanol or product recall.

On the British Virgin Islands the Ministry of Health warned about falsified hand sanitisers sold on their market (report ID 719716). The Nigerian National Agency for Food and Drugs Administration and Control (NAFDAC) seized 13 brands of falsified sanitizers in supermarkets and drug retail outlets (report ID 741664). All of them were stated as produced in Nigeria.

6.6 COVID-19 medicines

Remdesivir and corticosteroids have shown to be beneficial in the treatment of some well-defined subgroups of COVID-19 patients. For the month of September the MQM Globe does not hold reports of SF corticosteroids. In India a batch of Remdesivir was found to be substandard and has been withdrawn from the market (report ID 739155). Following the withdrawal there were concerns about supply shortages.

Many other repurposed and investigational antiviral and immune-based COVID-19 therapies are being trialled¹⁵. In addition patients turn to some medicines that are generally used for a cold, pain, fever or to boost the immunity. For all these medicines vigilance is needed considering the risk of substandard or falsified versions.

In September there was an article on falsified tocilizumab in India (report ID 748338). A medical store owner has been arrested for producing falsified tocilizumab using asthma medicines.

The Indian CDSCO released the results of their monthly routine quality tests. In August samples of prazosin, amoxicillin-clavulanic, and vitamin complexes containing vitamin C were reported as "Not Of Standard Quality" (report ID 727310).

In the USA there are litigations against some pharmacy stores for multiple reasons. One being that the "pharmacies failed to detect the sale of allegedly contaminated valsartan" (report ID 736772).

As in previous months SF sildenafil, a well-known medicine for erectile dysfunction, was reported. Studies for its use in the treatment of COVID-19 are ongoing¹⁶. A couple have been found guilty for importing sildenafil into the USA wrongly labelled as dietary supplements (report ID741030). In the UK a convenience store was allegedly illicitly selling this pharmacy controlled drug (report ID 746374). Two articles report on

¹⁵Infectious Diseases Data Observatory. COVID-19 Clinical Trials Interactive tool. Published 2020. Accessed October 19, 2020. https://www.iddo.org/tool/COVID-19-clinical-trials-interactive-tool

¹⁶ Ning Q (Tongji Hospital). A Pilot Study of Sildenafil in COVID-19. U.S. National Library of Medicine - Clinical Trials. Published 2020. Accessed October 14, 2020.

https://clinicaltrials.gov/ct2/show/NCT04304313?term=sildenafil&cond=COVID19&draw=2&rank=2

Lomakin FM (Universidad NAB). Sildenafil in COVID-19. U.S. National Library of Medicine - Clinical Trials. Published 2020. Accessed October 14, 2020.

https://clinicaltrials.gov/ct2/show/NCT04489446?term=sildenafil&cond=COVID19&draw=2&rank=1

sildenafil as a hidden drug ingredient in sexual enhancement products in the USA (report ID 722151) and in Nigeria (report ID 739955).

Falsified Lian Hua Qing Weng capsules were seized by the Philippine FDA (report ID 741529). The traditional medicine is used in China for the treatment of COVID-19, however in Philippines this indication is not approved. The US FDA sent a warning letter to Extrapharma, a company offering arbidol and claiming that it has activity against coronavirus, whereas Extrapharma has no approved drug application for its arbidol product and the FDA has not approved its use in COVID-19 (report ID 723098). Pharmacy owners were fined for the production and distribution of "Anti-Coronavirus" medication in Ukraine (report ID 740873). A seizure of medicines smuggled from Guinea into Liberia contained painkillers, multi vitamins, and cold caps (report ID 711310).

7. Annexes

The annexes contain the reports generated by the MQM-Globe using pre-defined search terms. The report IDs (six digits code) discussed in section 6 'Lay literature' are detailed in the annexes or available on the online MQM Globe¹⁷, using the report ID in the search box.

- 7.1 Vaccines
- 7.2 COVID-19 diagnostics
- 7.3 Personal Protective Equipment including sanitizers
- 7.4 COVID-19 medicines

_

¹⁷Infectious Diseases Data Observatory. Medicine Quality Monitoring Globe. Web Page. Published 2020. Accessed October 16, 2020. https://www.iddo.org/medicine-quality-monitoring-globe

Annex

7.1 Vaccines

Medicine Quality Monitoring Globe

October 22, 2020



This is a summary of the information available in the Medicine Quality Monitoring Globe for the search terms selected between the dates selected. For more information on the terminology used, caveats and the work of the medicine quality group please see the information at: https://www.iddo.org/medicine-quality

Non-Curated reports are those that have been automatically flagged as relevant by the system but have not been manually curated by the curators.

We would be grateful for any feedback on this summary and for the details of any reports that we may have missed.

Search vaccine AND (COVID-19 OR COVID OR SARS-CoV-2 OR CV OR Coronavirus OR CV19 OR CV-19 OR SARS OR CoV-2)

Start date	2020-09-01
End date	2020-09-30
Language	en
Number of Reports	5

1 Beware of Fraudulent Coronavirus Tests, Vaccines and Treatments - 2020-09-09

Publication date 2020-09-09

Create date 2020-09-10

Score 25.80

Report id 722073

Category Medical devices for disease prev, Antiviral others, Vaccine

Quality Old News

Source Not applicable

Curation Manually curated

Snippet: There are currently no FDA-approved drugs, including vaccines, to treat or prevent COVID-19. Products that claim to cure, treat, or prevent COVID-19 haven't been evaluated by the FDA for safety and effectiveness; they might be dangerous to you and your family.

Click here to see the Original Article

Table 1: Places for report 722073

Region Name	Country	Location	Latitude	Longitude
Americas	United States	United States	39.76	-98.5

Table 2: Drugs for report 722073

Medicine Name	Medicine Class	Action	ATC Code
			J07
chloroquine	Aminoquinolines	antimalarials	P01BA01

Table 3: Other Stories

ID	Title	Link
760715	Beware of Fraudulent Coronavirus Tests, Vaccines and	Link
	Treatments - 2020-09-21	

Notes: Meanwhile, some people and companies are trying to profit from this pandemic by selling unproven and illegally marketed products that make false claims, such as being effective against the coronavirus.

These fraudulent products that claim to cure, treat, or prevent COVID-19 haven't been evalu-

ated by the FDA for safety and effectiveness and might be dangerous to you and your family. [...] The FDA has also seen unauthorized fraudulent test kits for COVID-19 being sold online. Currently, the only way to be tested for COVID-19 is to talk to your health care provider.

At this time, the FDA has not authorized any COVID-19 test to be completely used and processed at home. The FDA has authorized the first COVID-19 test for home collection of samples, but those samples are to be sent to a laboratory for processing and test reporting. [...] There Are No Vaccines or Medicines for COVID-19, Yet [...] Fraudulent COVID-19 products can come in many varieties, including dietary supplements and other foods, as well as products claiming to be tests, drugs, medical devices, or vaccines.

The FDA has been working with retailers to remove dozens of misleading products from store shelves and online. The agency will continue to monitor social media and online marketplaces promoting and selling fraudulent COVID-19 products.

Recently, the FDA and the Federal Trade Commission issued warning letters to seven companies for selling fraudulent COVID-19 products. The products cited include teas, essential oils, tinctures, and colloidal silver (see product photosExternal Link Disclaimer on Flickr).

2 Fake COVID-19 Vaccine Manufacturing Unit Busted In Bargarh

Publication date 2020-09-26

Create date 2020-09-29

Score 23.38

Report id 742841

Category Other, Vaccine

Quality Falsified

Source Clandestine laboratory

Curation Manually curated

Snippet: Fake COVID-19 Vaccine Manufacturing Unit Busted In Bargarh OdishaTV

Click here to see the Original Article

Table 4: Places for report 742841

Region Name	Country	Location	Latitude	Longitude
Southern Asia	India	Bargarh	21.33348	83.61905

Table 5: Drugs for report 742841

Medicine Name	Medicine Class	Action	ATC Code
			J07

Table 6: Other Stories

ID	Title	Link
744196	Fake COVID-19 Drug Unit Busted In Bargarh	Link
762375	Class 7 Dropout Arrested In Odisha With Fake	Link
	COVID-19 Vaccines Which Claimed 100% Results	
749839	Odisha man tries to sell fake COVID-19 vaccine	Link
743696	Man arrested for making, selling COVID-19 vaccine'	Link
	in Odisha	
744234	Odisha man booked for making fake Covid-19 vaccine	Link
	with secret formula	
751680	Odisha man arrested for making fake covid-19 vaccine	Link
746065	Class 7 Dropout Arrested In Odisha With Fake	Link
	COVID-19 Vaccines Which Claimed 100% Results	

Table 6: Other Stories (continued)

ID	Title	Link
743012	Odisha man made fake Covid vaccine with top secret' formula, arrested	Link
744082	Case To Remove Mosque In Mathura; Man Selling Fake COVID Vaccines + More Top News	Link
757680	Odisha man tries to sell fake COVID-19 vaccine	Link
744883	School dropout comes up with fake Covid-19 vaccine in Odisha, arrested	Link
744631	Odisha man arrested for making fake covid-19 vaccine	Link
749263	Odisha man made fake Covid vaccine with top secret' formula, arrested	Link
743376	Odisha man booked for making fake COVID-19 vaccine	Link
743382	Man booked for manufacturing fake Covid-19 vaccine	Link
743639	Man booked for making fake Covid vaccine	Link
743384	Odisha man arrested for manufacturing fake Covid-19 vaccine	Link
743641	32-year-old Odisha man booked for making fake COVID-19 vaccine	Link
742875	Fake Covid Drug Manufacturing Unit Busted In Odisha, 1 Held	Link
743643	Man booked for making fake Covid vaccine in Odisha	Link
743644	Agency News — Fake COVID-19 Vaccine: Odisha Man Booked For Making Fake Anti-Coronavirus Drugs	Link
750842	Odisha man booked for making fake COVID-19 vaccine	Link
743164	Man arrested for manufacturing fake COVID-19 vaccine in Odisha	Link

Notes: Bargarh: In a joint operation, drug inspectors from Sambalpur and Bargarh and a police team busted a fake Covid-19 vaccine manufacturing unit at Rushuda village under the Bheden Police Station in Bargarh, Saturday. The team seized large quantity of fake Covid-19 vaccines, packets, powder and chemical materials from the unit which was run by one Prahalad Bishi. "After receiving a tip-off we raided the unit and found Bishi preparing a large quantity of fake Covid-19 vaccines. All the fake vaccines with Covid-19 markings (stickers) have been seized," stated drug inspector Sasmita Deheri. The counterfeit drug was to be supplied to the open market as Covid-19 vaccines, police said. Further investigation into the case is underway.

2020-10-22 5

3 Darknet Dealers are Selling COVID-19 Test Kits for Thousands of Dollars

Publication date 2020-09-11

Create date 2020-09-11

Score 22.19

Report id 723812

Category Medical device for screening/dia, Medical devices for disease prev, Vaccine, Anti-malarial

Quality Diverted/Unregistered

Source Website(s)

Curation Manually curated

Snippet: Darknet Dealers are Selling COVID-19 Test Kits for Thousands of Dollars VICE

Click here to see the Original Article

Table 7: Places for report 723812

Region Name	Country	Location	Latitude	Longitude
Americas	United States	United States	39.76	-98.5
		Earth	0	0

Table 8: Drugs for report 723812

Medicine Name	Medicine Class	Action	ATC Code
			J07
hydroxychloroquine	Aminoquinolines	antimalarials	P01BA02

Notes: VICE News spoke to one vendor who claims he's made more than \$1.4 million USD selling kits to hospitals and geriatric homes around the world. [...] Acting on a tip-off from connections in China and Hong Kong, the US-based businessman pulled together a network of like-minded entrepreneurs who bought thousands of COVID-19 IgM/IgG Rapid Tests directly from a handful of factories in Germany and Korea. [...] Speaking to VICE News over Wickr, Jason (not his real name) revealed that he's sold 8,000 COVID-19 testing kits on the dark web to dateeach one going for \$180 USD a piece. Half of those were snapped up by medical centres in Italy and the United States; 1,000 went to a geriatric home in an unspecified location; while another 3,000 were bought out by a single individual, who Jason suspects was acting on behalf of a mystery government or hospital. [...] Jason isn't the only illegal operator who's found a way to profiteer during the pandemic. VICE News found dozens of online dealers peddling

spurious coronavirus "vaccines", along with sheets of hydroxychloroquine pills and the blood of recovered COVID-19 patients for nearly \$16,000 USD per liter. [...] "Many of these vendors take advantage of the panic," he said. "There are some who promise to sell all kinds of remedies which are probably fake, [while] others sell protective gear like masks and hand santizers [amid] a worldwide shortage [and] we have strong reason to believe it's of low quality. We even know of some groups who sell used facemasks." [...] Any type of protective gear that hasn't been approved for use by the relevant authorities is not safe for use, says Maimon, who strongly advises against relying on any type of health-related commodity that has been acquired on the dark web.

"Of course there are a lot of fake drugs and commodities out there as well," he adds, "so consumers need to be vigilant regarding the manufacturers and the vendors they purchase from."

If Jason can be taken at his word, though, he's in the business of hoarding and selling coronavirus test kits for reasons that are more altruistic than financial suggesting that he's the one who doesn't have time for anyone not taking the COVID crisis seriously.

4 Fake Covid-19 testing kits, corona-killing machines on offer on Twitter & Instagram, unapproved herbal pr

Publication date 2020-09-03 Create date 2020-09-07 Score 20.82 Report id 713833 Category Antiviral others Quality Diverted/Unregistered Source Website(s) Curation Manually curated

Snippet: Fake Covid-19 testing kits, corona-killing machines on offer on Twitter & Instagram, unapproved herbal pr Times of India

Click here to see the Original Article

Table 9: Places for report 713833

Region Name	Country	Location	Latitude	Longitude
Americas	United States	United States	39.76	-98.5
		Earth	0	0

Table 10: Other Stories

ID	Title	Link
714167	Fake Covid-19 products, including unapproved herbal	Link
	products from India, available on Twitter, Instagram	

Notes: From essential oils and herbal concoctions that claim to keep Covid-19 (https://timesofindia.indiatimes.c 19) at bay to a USD 6,000 portable device charged by negative ions that can kill coronavirus, counterfeit health products, illegal or unapproved testing kits and purported cures are on offer on popular social media platforms like Twitter (https://timesofindia.indiatimes.com/topic/Twitter) and Instagram, leading to a cyber syndemic' a digital contagion combined with a health epidemic an Indian scientist's team in the US has warned. In a new study published in the Journal of Medical Internet Research Public Health and Surveillance last week, researchers at the University of California San Diego School of Medicine found two popular platforms. Twitter and Instagram flooded with counterfeit goods related to Covid-19. "We found alleged immunity boosting kits' being advertised on Twitter. Other products included so-called herbal concoctions and antiviral drops' claiming to serve as a remedy for Covid-19. An Indian user had

posted on something called Nirogmaya NoCorona' antiviral preventive drops for coronavirus protection. It included hyperlinks to an external e-commerce site where the product could be purchased. Both have been removed since then," Vidya Purushothaman, study co-author and research associate at the UC San Diego School of Medicine, told TOI. Timothy Mackey, associate adjunct professor and lead author of the study, added that their team detected nearly 2,000 fraudulent postings likely tied to fake (https://timesofindia.indiatimes.com/topic/fake) Covid-19 health products, financial scams and other consumer risk on the two platforms between March to May 2020 alone. [...] Fraudsters and illegal sellers have a very easy entry point in social media platforms where organic and user-generated content can easily be posted, you can use hashtags to curate content for the audiences you want and it is low effort compared to creating an e-commerce selling account or a dark web marketplace listing. And even if their posts are removed, it is easy to create another account and simply repost the same content." Mackey's team, which continues to conduct online surveillance for counterfeit and fake Covid-19-related products, said the types of products are changing as availability in the legitimate marketplace changes. "For example, we see less Covid-19 testing kits on offer now that there is increased testing capacity. Illegal online pharmacies that require no prescription continue to sell Covid-19 related drugs." Between March and May, the fake products came in waves the "first wave" included preventative treatments like herbal remedies that came up immediately after the pandemic's severity became apparent, the study found. This was followed by a much larger "second wave" that included unapproved testing kits and diagnostic products ranging from USD 4 to USD 398. A questionable product described as a "portable hospital" device that claimed to use a negative ion current to treat Covid-19 and other viruses was priced at USD 6,000. Mackey said a third wave of fake pharmaceutical treatments is now materialising and will worsen when public health officials announce development of an effective vaccine or other therapeutic treatments. "We are in the midst of, what I would like to call, a cyber syndemic. It originates from the term syndemic', which generally means when two epidemics are going on at the same time and are interacting with each other. In this context, we are dealing with both an outbreak of Covid-19 from a public health perspective and an outbreak and digital contagion of Covid-19-related cybercrime."

5 Mass Bacterial Infection from Chinese Pharmaceutical Company Casts Doubts on COVID Vaccine

Publication date 2020-09-17

Create date 2020-09-18

Score 16.00

Report id 732310

Category Vaccine, Veterinary medicines

Quality Substandard

Source Manufacturer

Curation Manually curated

Snippet: Mass Bacterial Infection from Chinese Pharmaceutical Company Casts Doubts on COVID Vaccine American Council on Science and Health

Click here to see the Original Article

Table 11: Places for report 732310

Region Name	Country	Location	Latitude	Longitude
Eastern Asia	China	People's Republic of China	35	105

Table 12: Drugs for report 732310

Medicine Name	Medicine Class	Action	ATC Code
	Brucellosis vac- cines	bacterial vaccines	J07AD

Notes: In China, brucellosis is more common and outbreaks still occur. However, the most recent brucellosis outbreak, which has infected at least 3,245 people, surely is a first: The source of the infection was not contaminated food but a pharmaceutical factory. How on earth could that happen?

Well, there's more than one way to get brucellosis. Consuming raw or unpasteurized food is one way. Another is to touch animal products contaminated with the bacteria, which can enter the body through breaks in the skin. Yet another route is inhalation. While this is mostly a threat to those who come into close contact with animals or animal products, like slaughterhouse workers, infection via inhalation can occur if the bacteria are aerosolized. And that's exactly what happened in China.

CNN has reported that a pharmaceutical company that was manufacturing brucellosis vaccines

for animals was using expired disinfectants. Waste gas emitted from the factory contained live Brucella, which then wafted its way into the city of Lanzhou, infecting thousands of people.

Who Wants a Chinese COVID Vaccine?

This news doesn't come at a particularly good time for China, which has been blamed for causing and then covering up the ongoing coronavirus pandemic. Like in several other countries, Chinese companies are working to produce a vaccine against coronavirus. One company, called CanSinoBIO, is testing their vaccine in soldiers. Lucky them!

Not to be jingoistic, but there's a reason why things like this don't happen in the United States, Europe, Japan, or other advanced nations: A culture of safety and regulation when it comes to industries that have the power to cure or kill its customers. China simply does not have that. Yet, the U.S. (and many other countries) use Chinese ingredients in the pharmaceutical drugs that we manufacture. As I wrote for USA Today, this is a substantial threat to national security and public health.

Incidents like the mass infection described above should further stiffen our resolve to deal strongly with China, forcing them to adopt standards that are acceptable to Americans and citizens of other advanced nations. Until then, China poses an unnecessary risk to global health. As a case-in-point, who among you would actually sign up for a Chinese COVID vaccine?

Annex

7.2 COVID-19 diagnostics

Medicine Quality Monitoring Globe

October 22, 2020



This is a summary of the information available in the Medicine Quality Monitoring Globe for the search terms selected between the dates selected. For more information on the terminology used, caveats and the work of the medicine quality group please see the information at: https://www.iddo.org/medicine-quality

Non-Curated reports are those that have been automatically flagged as relevant by the system but have not been manually curated by the curators.

We would be grateful for any feedback on this summary and for the details of any reports that we may have missed.

Search ("RDT" OR

"lateral flow assay" OR "LFA" OR "rapid diagnostic test" OR "antigen test" OR "test cassette" OR "Reverse Transcription Polymerase Chain Reaction" OR "cassette test" OR "coronavirus rapid test kit" OR "RT-PCR" OR "testing kit" OR "qPCR" OR "antibody test" OR "PCR" OR "polymerase chain reaction" OR "ELISA") AND ("CV19" OR "" OR "" OR "SARS" OR "CoV-2" OR "vi rt corona" OR "" OR "COVID-19" OR "COVID" OR "" OR "" OR "SARS-CoV-2" OR "CV" OR "Coronavirus" OR "CV-19" OR "" OR "")

 Start date
 2020-09-01

 End date
 2020-09-30

Language

Number of Reports

8

1 Nearly 4 lakh fake COVID test kits seized in Noida; 1 arrested

Publication date 2020-09-29

Create date 2020-10-01

Score 23.72

Report id 746390

Category Medical device for screening/dia

Quality Falsified

Source Clandestine laboratory

Curation Manually curated

Snippet: Nearly 4 lakh fake COVID test kits seized in Noida; 1 arrested Devdiscourse

Click here to see the Original Article

Table 1: Places for report 746390

Region Name	Country	Location	Latitude	Longitude
Southern Asia	India	Noida	28.58	77.33

Table 2: Other Stories

ID	Title	Link
747269	Nearly 4 lakh fake Covid test kits seized in Noida; 1	Link
	arrested	
750128	Nearly 4 Lakh Fake COVID-19 Test Kits Seized In	Link
	Noida; 1 Arrested	
755647	Nearly 4 lakh fake COVID test kits seized in Noida; 1	Link
	arrested	
748784	Nearly 4 lakh fake COVID-19 test kits seized in Noida;	Link
	1 arrested	
746748	Man held for manufacturing fake Covid-19 test pack-	Link
	ages	

Notes: The Noida Police on Tuesday busted a company manufacturing fake test kits for COVID-19 and arrested a person, officials said here. Nearly four lakh fake rapid test kits were recovered from the company located in Sector 7, under the Sector 20 police station area, they said. "The fake company was busted a day after a complaint about it was made by a representative of a COVID-19 test kit-making company.// The Noida Police on Tuesday busted a company manufacturing fake test kits for COVID-19 and arrested a person, officials said here. Nearly

four lakh fake rapid test kits were recovered from the company located in Sector 7, under the Sector 20 police station area, they said.

"The fake company was busted a day after a complaint about it was made by a representative of a COVID-19 test kit-making company. This company had claimed that its forged labels are being used on fake testing kits," a police spokesperson said. Rajesh Prasad, who runs this fake company, has been arrested. He was picked up from his home in Delhi's Ashok Nagar, he said. According to the police, 3.97 lakh pouches carrying fake antibodies rapid test kits for coronavirus were seized from the company. An FIR has been lodged under the Copyright Act, 1957 at the Sector 20 police station, and further proceedings are underway, the police said.

2 Fake Covid-19 testing kits, corona-killing machines on offer on Twitter & Instagram, unapproved herbal pr

Publication date 2020-09-03 Create date 2020-09-07 Score 22.50Report id 713833 Category Antiviral others Quality Diverted/Unregistered Source Website(s) Curation Manually curated

Snippet: Fake Covid-19 testing kits, corona-killing machines on offer on Twitter & Instagram, unapproved herbal pr Times of India

Click here to see the Original Article

Table 3: Places for report 713833

Region Name	Country	Location	Latitude	Longitude
Americas	United States	United States	39.76	-98.5
		Earth	0	0

Table 4: Other Stories

ID	Title	Link
714167	Fake Covid-19 products, including unapproved herbal	Link
	products from India, available on Twitter, Instagram	

Notes: From essential oils and herbal concoctions that claim to keep Covid-19 (https://timesofindia.indiatimes.c 19) at bay to a USD 6,000 portable device charged by negative ions that can kill coronavirus, counterfeit health products, illegal or unapproved testing kits and purported cures are on offer on popular social media platforms like Twitter (https://timesofindia.indiatimes.com/topic/Twitter) and Instagram, leading to a cyber syndemic' a digital contagion combined with a health epidemic an Indian scientist's team in the US has warned. In a new study published in the Journal of Medical Internet Research Public Health and Surveillance last week, researchers at the University of California San Diego School of Medicine found two popular platforms. Twitter and Instagram flooded with counterfeit goods related to Covid-19. "We found alleged immunity boosting kits' being advertised on Twitter. Other products included so-called herbal concoctions and antiviral drops' claiming to serve as a remedy for Covid-19. An Indian user had

posted on something called Nirogmaya NoCorona' antiviral preventive drops for coronavirus protection. It included hyperlinks to an external e-commerce site where the product could be purchased. Both have been removed since then," Vidya Purushothaman, study co-author and research associate at the UC San Diego School of Medicine, told TOI. Timothy Mackey, associate adjunct professor and lead author of the study, added that their team detected nearly 2,000 fraudulent postings likely tied to fake (https://timesofindia.indiatimes.com/topic/fake) Covid-19 health products, financial scams and other consumer risk on the two platforms between March to May 2020 alone. [...] Fraudsters and illegal sellers have a very easy entry point in social media platforms where organic and user-generated content can easily be posted, you can use hashtags to curate content for the audiences you want and it is low effort compared to creating an e-commerce selling account or a dark web marketplace listing. And even if their posts are removed, it is easy to create another account and simply repost the same content." Mackey's team, which continues to conduct online surveillance for counterfeit and fake Covid-19-related products, said the types of products are changing as availability in the legitimate marketplace changes. "For example, we see less Covid-19 testing kits on offer now that there is increased testing capacity. Illegal online pharmacies that require no prescription continue to sell Covid-19 related drugs." Between March and May, the fake products came in waves the "first wave" included preventative treatments like herbal remedies that came up immediately after the pandemic's severity became apparent, the study found. This was followed by a much larger "second wave" that included unapproved testing kits and diagnostic products ranging from USD 4 to USD 398. A questionable product described as a "portable hospital" device that claimed to use a negative ion current to treat Covid-19 and other viruses was priced at USD 6,000. Mackey said a third wave of fake pharmaceutical treatments is now materialising and will worsen when public health officials announce development of an effective vaccine or other therapeutic treatments. "We are in the midst of, what I would like to call, a cyber syndemic. It originates from the term syndemic', which generally means when two epidemics are going on at the same time and are interacting with each other. In this context, we are dealing with both an outbreak of Covid-19 from a public health perspective and an outbreak and digital contagion of Covid-19-related cybercrime."

3 Darknet Dealers are Selling COVID-19 Test Kits for Thousands of Dollars

Publication date 2020-09-11

Create date 2020-09-11

Score 21.47

Report id 723812

Category Medical device for screening/dia, Medical devices for disease prev, Vaccine, Anti-malarial

Quality Diverted/Unregistered

Source Website(s)

Curation Manually curated

Snippet: Darknet Dealers are Selling COVID-19 Test Kits for Thousands of Dollars VICE

Click here to see the Original Article

Table 5: Places for report 723812

Region Name	Country	Location	Latitude	Longitude
Americas	United States	United States	39.76	-98.5
		Earth	0	0

Table 6: Drugs for report 723812

Medicine Name	Medicine Class	Action	ATC Code
			J07
hydroxychloroquine	Aminoquinolines	antimalarials	P01BA02

Notes: VICE News spoke to one vendor who claims he's made more than \$1.4 million USD selling kits to hospitals and geriatric homes around the world. [...] Acting on a tip-off from connections in China and Hong Kong, the US-based businessman pulled together a network of like-minded entrepreneurs who bought thousands of COVID-19 IgM/IgG Rapid Tests directly from a handful of factories in Germany and Korea. [...] Speaking to VICE News over Wickr, Jason (not his real name) revealed that he's sold 8,000 COVID-19 testing kits on the dark web to dateeach one going for \$180 USD a piece. Half of those were snapped up by medical centres in Italy and the United States; 1,000 went to a geriatric home in an unspecified location; while another 3,000 were bought out by a single individual, who Jason suspects was acting on behalf of a mystery government or hospital. [...] Jason isn't the only illegal operator who's found a way to profiteer during the pandemic. VICE News found dozens of online dealers peddling

spurious coronavirus "vaccines", along with sheets of hydroxychloroquine pills and the blood of recovered COVID-19 patients for nearly \$16,000 USD per liter. [...] "Many of these vendors take advantage of the panic," he said. "There are some who promise to sell all kinds of remedies which are probably fake, [while] others sell protective gear like masks and hand santizers [amid] a worldwide shortage [and] we have strong reason to believe it's of low quality. We even know of some groups who sell used facemasks." [...] Any type of protective gear that hasn't been approved for use by the relevant authorities is not safe for use, says Maimon, who strongly advises against relying on any type of health-related commodity that has been acquired on the dark web.

"Of course there are a lot of fake drugs and commodities out there as well," he adds, "so consumers need to be vigilant regarding the manufacturers and the vendors they purchase from."

If Jason can be taken at his word, though, he's in the business of hoarding and selling coronavirus test kits for reasons that are more altruistic than financial suggesting that he's the one who doesn't have time for anyone not taking the COVID crisis seriously.

4 FBI and local authorities warn about fraudulent COVID-19 testing scheme

Publication date 2020-09-07

Create date 2020-09-09

Score 20.52

Report id 719163

Category Medical devices for disease prev

Quality Falsified

Source Website(s)

Curation Manually curated

Snippet: FBI and local authorities warn about fraudulent COVID-19 testing scheme WHNT News 19

Click here to see the Original Article

Table 7: Places for report 719163

Region Name	Country	Location	Latitude	Longitude
Americas	United States	Madison	34.69926	-86.74833

Table 8: Other Stories

ID	Title	Link
737205	FBI and local authorities warn about fraudulent COVID-19 testing scheme	Link
726515	FBI and local authorities warn about fraudulent COVID-19 testing scheme	Link

Notes: The FBI and local law enforcement have put out an alert about the latest COVID-19 scam to hit the streets. In a social media post retweeted by the Madison City Police department, the FBI warned about fraudsters selling fake COVID-19 tests door-to-door. The tests could potentially both bilk people out of their hard-earned money and put their health in jeopardy too. Beware of individuals trying to sell at-home #COVID19 test kits. Only a trusted physician or health care provider should assess your health and approve requests for testing. [...] "The Coronavirus pandemic is a time for Americans to pull together, but it is not a time for us to let our guard down," said Chris Schrank, Assistant Inspector General of the US Department of Health and Human Resources (HHS), speaking in a recent video posted online. The HHS is coordinating with the FBI on the effort to warn people about the scam. "Scammers are

out active right now. They are preying on the public's fears by offering COVID-19 tests or cures in exchange for personal details," Schrank said. The FBI said many of the scammers are also hawking fake testing kits through telemarketing calls and social media platforms. Those who use them could be at risk of receiving a potentially life-threatening false-negative test for COVID-19 and going untreated for the virus. "That's sad. What I hear is somebody is going to get real sick and when they get real sick, since I do work in the medical field, we're going to have to take care of more people," said Matthew Darnell, a healthcare worker in Huntsville. "What if somebody is selling something fake to someone you love and you're selling something fake too. Why would you do that?" Many of the scammers are promising free tests or treatment in order to gain access people's personal identity. The scammers often ask personal and health insurance information, dates of birth, Social Security numbers, and financial data. "I would just think anybody should be leery of someone selling door to door anything that has to do with medical," said Hope Sealy of Huntsville. The FBI said seeking people medical advice should only trust healthcare professions when it comes to anything to do with the Coronavirus and your health in general. [...]

5 Beware of Fraudulent Coronavirus Tests, Vaccines and Treatments - 2020-09-09

Publication date 2020-09-09

Create date 2020-09-10

Score 20.49

Report id 722073

Category Medical devices for disease prev, Antiviral others, Vaccine

Quality Old News

Source Not applicable

Curation Manually curated

Snippet: There are currently no FDA-approved drugs, including vaccines, to treat or prevent COVID-19. Products that claim to cure, treat, or prevent COVID-19 haven't been evaluated by the FDA for safety and effectiveness; they might be dangerous to you and your family.

Click here to see the Original Article

Table 9: Places for report 722073

Region Name	Country	Location	Latitude	Longitude
Americas	United States	United States	39.76	-98.5

Table 10: Drugs for report 722073

Medicine Name	Medicine Class	Action	ATC Code
			J07
chloroquine	Aminoquinolines	antimalarials	P01BA01

Table 11: Other Stories

ID	Title	Link
760715	Beware of Fraudulent Coronavirus Tests, Vaccines and	Link
	Treatments - 2020-09-21	

Notes: Meanwhile, some people and companies are trying to profit from this pandemic by selling unproven and illegally marketed products that make false claims, such as being effective against the coronavirus.

These fraudulent products that claim to cure, treat, or prevent COVID-19 haven't been evalu-

ated by the FDA for safety and effectiveness and might be dangerous to you and your family. [...] The FDA has also seen unauthorized fraudulent test kits for COVID-19 being sold online. Currently, the only way to be tested for COVID-19 is to talk to your health care provider.

At this time, the FDA has not authorized any COVID-19 test to be completely used and processed at home. The FDA has authorized the first COVID-19 test for home collection of samples, but those samples are to be sent to a laboratory for processing and test reporting. [...] There Are No Vaccines or Medicines for COVID-19, Yet [...] Fraudulent COVID-19 products can come in many varieties, including dietary supplements and other foods, as well as products claiming to be tests, drugs, medical devices, or vaccines.

The FDA has been working with retailers to remove dozens of misleading products from store shelves and online. The agency will continue to monitor social media and online marketplaces promoting and selling fraudulent COVID-19 products.

Recently, the FDA and the Federal Trade Commission issued warning letters to seven companies for selling fraudulent COVID-19 products. The products cited include teas, essential oils, tinctures, and colloidal silver (see product photosExternal Link Disclaimer on Flickr).

6 Surge In Illegal Drugs And COVID-19 Counterfeits During Pandemic Shipments

Publication date 2020-09-24

Create date 2020-09-28

Score 15.32

Report id 740485

Category Medical device for screening/dia, Medical devices for disease prev, Psychoactive substance

Quality Falsified

Source Unknown

Curation Manually curated

Snippet: Surge In Illegal Drugs And COVID-19 Counterfeits During Pandemic Shipments CBS Chicago

Click here to see the Original Article

Table 12: Places for report 740485

Region Name	Country	Location	Latitude	Longitude
Americas	United States	Chicago	41.85003	-87.65005

Table 13: Other Stories

ID	Title	Link
746326	Surge In Illegal Drugs And COVID-19 Counterfeits During Pandemic Shipments	Link

Notes: CHICAGO (CBS) An explosion of illegal drugs and an increasing cache of counterfeits are flowing through one of the busiest mail facilities in the country, right here in Chicago. [...] Between March and August of last year, CBP agents in the Chicago Field Office seized more than 8,800 pounds of narcotics.

Between March and August of this year? That number exploded to more than 21,000 pounds. [...] Among phonies found? Prescription drugs, designer drugs, designer brands like Nike and Cartier. You name it. But a new addition to 2020 seizures is pandemic products.

There were COVID 19 test cards, rapid kits, and detection kits in just a day's worth of the phony COVID 19 products coming through Chicago's International Mail Facility.

Campbell explained the risk of some of the fake tests for people who wittingly or unwittingly order them: "They have a false negative but they may or may not be actually positive. But

they're using a bad test in the hopes that it's going to tell them what they want to hear."[...] Unfortunately, there's no sniff test for fake COVID test or counterfeit PPE.

CBP has to rely on a system of radiation screening, x-ray screening and physical inspections. It's been a grueling workflow during the pandemic. [...] The Chicago Field Office receives about 57 million shipments every year. Campbell said the majority of counterfeits come from China.

7 Rajasthan MP questions Covid test at Parliament - jaipur

Publication date 2020-09-15

Create date 2020-10-12

Score 14.09

Report id 729474

Category Medical device for screening/dia

Quality Substandard or Falsified

Source Unknown

Curation Manually curated

Snippet: Rajasthan MP questions Covid test at Parliament - jaipur Hindustan Times

Click here to see the Original Article

Table 14: Places for report 729474

Region Name	Country	Location	Latitude	Longitude
Southern Asia	India	Jaipur	26.91962	75.78781

Notes: Rajasthan MP Hanuman Beniwal has dismissed Covid-19 test done at Parliament as "fake" after it found him to be Covid 19 positive more than a month after he was declared recovered from the disease after successful treatment at a Jaipur hospital in August. To confirm his negative status, the MP got his sample tested again by the Jaipur hospital, which was found to be negative, Beniwal said. Beniwal, MP from Nagaur, gave a sample for testing at Lok Sabha on September 11 and was informed three days later that he had tested positive. The report left Beniwal puzzled since he had already undergone treatment at SMS Hospital in Jaipur after testing positive on July 26 and even completed the 14-day quarantine period after his discharge on August 6. "After learning about my report from LS secretariat, I spoke to doctors at Jaipur who suggested that I get tested again here. I gave my sample and the SMS Hospital report says I am negative," the MP said. Doctors at SMS Hospital said that he was fit and could even donate plasma for treatment of Covid-19 patients, Beniwal added. He said between July 26 and Monday, he has tested negative thrice and called the Delhi test fake. "I appeal to Lok Sabha Speaker to probe this. False positive is harmless but imagine if a positive person is sitting in the Parliament because he has falsely been tested negative," he said. Beniwal is the founder of Rashtriya Loktantrik Party (RLP), which is supporting National Democratic Alliance (NDA) at Centre. "What pains me more is the fact that despite me being an NDA ally, no one from the government has spoken to me yet to find out about this test fraud," Beniwal said. He said he was admitted to Rajasthan University of Health Sciences (RUHS) hospital in Jaipur on July 30 for Covid-19 care. His second test, conducted on July 31, was also positive. He was discharged on August 7 after he tested negative. After that he was in home isolation for 14 days. [testing kit]

8 Kenya raids shop selling fake coronavirus kits as Liberia confirms first case

Publication date 2020-09-02

Create date 2020-09-07

Score 12.72

Report id 713707

Category Medical devices for disease prev

Quality Falsified

Source Unspecified outlet

Curation Manually curated

Snippet: Kenya raids shop selling fake coronavirus kits as Liberia confirms first case Reuters Africa

Click here to see the Original Article

Table 15: Places for report 713707

Region Name	Country	Location	Latitude	Longitude
Eastern Africa	Kenya	Republic of Kenya	1	38

Notes: Kenyan authorities raided a shop on Monday that was alleged to be selling fake coronavirus testing kits, as the World Health organisation confirmed there were at least 327 cases on the African continent. Police detained staff and locked the facility, withness told Reuters journalists at the scene, after the shop had been advertising testing kits online.

Annex

7.3 Personal Protective Equipment including sanitizers

Medicine Quality Monitoring Globe

October 22, 2020



This is a summary of the information available in the Medicine Quality Monitoring Globe for the search terms selected between the dates selected. For more information on the terminology used, caveats and the work of the medicine quality group please see the information at: https://www.iddo.org/medicine-quality

Non-Curated reports are those that have been automatically flagged as relevant by the system but have not been manually curated by the curators.

We would be grateful for any feedback on this summary and for the details of any reports that we may have missed.

Search "Personal protective equipment" OR "disinfectant" OR "PPE" OR "santiser" OR "sanitizing" OR "apron" OR "iodoform" OR "n95" OR "gowns" OR "visor" OR "gloves" OR "goggles" OR "sanitizer" OR "respirator" OR "mask"

Start date	2020-09-01
End date	2020-09-30
Language	en
Number of Reports	36

1 Boston border patrol officers seize more than 20,000 counterfeit N95 masks

Publication date 2020-09-17

Create date 2020-09-18

Score 30.47

Report id 732067

Category Medical devices for disease prev

Quality Falsified

Seaport

Curation Manually curated

Snippet: Boston border patrol officers seize more than 20,000 counterfeit N95 masks Boston News, Weather, Sports — WHDH 7News

Click here to see the Original Article

Table 1: Places for report 732067

Region Name	Country	Location	Latitude	Longitude
Americas	United States	Boston	42.35843	-71.05977

Table 2: Other Stories

ID	Title	Link
732936	More than 20,000 counterfeit N95 face masks from	Link
	Hong Kong seized by border patrol officers in Boston	
733463	Customs and Border Protection seize over 20K fake	Link
	N95 masks in Boston — TheHill	
732237	20,000 Counterfeit N95 Masks Seized By CBP In	Link
	Boston	
732861	CBP intercepts 20000 counterfeit N95 masks in Boston	Link
732117	\$163K in Fake N95 Masks Seized in Shipment at	Link
	Boston's Port	
739299	CBP Intercepts 20000 Counterfeit N95 Masks in	Link
	Boston	

Notes: BOSTON (WHDH) - U.S. Customs and Border Protection assigned to the International Cargo Port in Boston seized more than 20,000 counterfeit N95 respirator masks earlier this month, officials announced Thursday.

Officers investigating a suspicious shipment from Hong Kong on Sept. 2 detained 43 boxes that appeared to contain counterfeit masks, according to a news release.

CBP specialists later determined that a total of 20,400 masks valued at about \$163,200 were indeed fake.

"Counterfeit personal protective equipment puts frontline workers and the general public's health at risk," said Michael Denning, Director of Field Operations for the Boston Field Office. "CBP officers and our trade teams are trained to identify and intercept these dangerous goods before they can do harm to our communities and the American consumer."

Certain organizations have been attempting to exploit the limited supply of and increased demand for some pharmaceuticals, personal protective equipment and other medical goods required to respond to the COVID-19 pandemic, CBP officials warned.

2 Virginia Beach company sues after receiving thousands of dollars worth of alleged counterfeit N95 masks

Publication date 2020-09-02

Create date 2020-09-04

Score 26.02

Report id 712513

Category Medical devices for disease prev

Quality Falsified

Source Distributor/Wholesaler

Curation Manually curated

Snippet: Virginia Beach company sues after receiving thousands of dollars worth of alleged counterfeit N95 masks WAVY.com

Click here to see the Original Article

Table 3: Places for report 712513

Region Name	Country	Location	Latitude	Longitude
Americas	United States	Virginia Beach	36.85293	-75.97799

Notes: A Virginia Beach company is suing after thousands of dollars worth of N95 and KN95 respirator masks they ordered early in the coronavirus pandemic ended up being counterfeit, according to a federal lawsuit. MJL Enterprises, a government contractor, filed the lawsuit last week in Norfolk against Eco Lighting USA Limited Liability Company, based in New Jersey. According to the lawsuit, Eco Lighting reached out to MJL in late March when N95 masks and other personal protective equipment were in short supply and said it had a large supply of "FDA approved" N95 and KN95 for sale. MJL intended to resell the masks to its federal clients. MJL ended up buying \$17,000 worth of N95s and \$387,500 worth of KN95s from Eco Lighting on April 9, according to the lawsuit, and orally requested that they provide proof the masks were FDA certified. However MJL didn't get the masks within 14 days as required by the purchase agreement, and requested a full refund on June 2, the lawsuit states. After Eco Lighting refused, MJL learned on June 11 and 12 the certificates of registration provided by Eco Lighting were not issued by the noted registering agents and the Chinese manufacturers on the certificates didn't claim to produce the "FDA certified masks," the lawsuit states. MJL stopped reselling the masks on June 12 after the findings, with several customers reaching and saying the masks were not genuine. MJL has requested a jury trial and more than \$600,000 in damages.

3 Illicit trade during Covid19 & Bangladesh

Publication date 2020-09-26

Create date 2020-09-29

Score 24.79

Report id 743276

Category Medical devices for disease prev

Quality Substandard or Falsified

Source Unknown

Curation Manually curated

Snippet: Illicit trade during Covid19 & Bangladesh The Financial Express

Click here to see the Original Article

Table 4: Places for report 743276

Region Name	Country	Location	Latitude	Longitude
Southern Asia	Bangladesh	Bangladesh	24	90

Notes: An immediate outcome of the Covid-19 is a booming black market of medical equipment. [...] So, it is not surprising that Bangladesh would see the illicit trade of medical equipment during the pandemic. To ensure smooth supply of Personal Protective Equipment (PPE), the country has already imposed temporary export prohibition on two products- surgical mask and disinfectants (hand sanitisers). The country usually maintains one of the highest averages MFN (Most Favoured Nation)-applied tariffs on (PPE). While global average import tariff on PPE is 11.50 per cent, the rate in the country is 19.80 per cent, according to the World Trade Organization (WTO). The authorities waived all the customs duties on safety kits and related raw materials at the last week of March, after the outbreak of deadly virus. As demand increased, local producers came to supply some PPE equipment like face masks and protective clothing. Within a short time span, different types of face masks became available in the market, although most of those were ineffective due to a lack of quality. Moreover, the country's standard setting and testing body didn't provide any rules or standards for face mask or other PPE equipment which meant product quality and health and safety was compromised. A lack of clear instruction to maintain standards, or an absence of guidelines coupled with limited monitoring allowed criminal gangs to sell sub-standard PPE. This is not directly linked with illicit trade of medical products as the country's total trade in medical items is still small.

2020-10-22 5

4 SA's PPE disgrace: 'substandard' anti-covid masks fail quality tests

Publication date 2020-09-05

Create date 2020-09-07

Score 24.48

Report id 716864

Category Medical devices for disease prev

Quality Substandard

Source Unknown

Curation Manually curated

Snippet: SA's PPE disgrace: 'substandard' anti-covid masks fail quality tests TimesLIVE

Click here to see the Original Article

Table 5: Places for report 716864

Region Name	Country	Location	Latitude	Longitude
Southern Africa	South Africa	South Africa	-29	24

Table 6: Other Stories

ID	Title	Link
717159	SA's PPE disgrace: 'substandard' anti-Covid masks fail quality tests	Link
718703	Using the wrong masks could be more dangerous than no mask	Link

Notes: Four companies have been charged and dozens more are being investigated for providing substandard personal protective equipment (PPE), which heightens the risk of spreading Covid-19 and endangers health-care workers.

The South African Health Products Regulatory Authority (Sahpra) confirmed that alongside the police's organised crime unit, the Hawks and the Special Investigating Unit (SIU), it is investigating PPE manufacturers and suppliers for "the supply of substandard or falsified PPE" intended for use in health-care institutions, including aged-care facilities...

5 Substandard hand sanitizers in the market threaten public health

Publication date 2020-09-16
Create date 2020-09-18
Score 19.18
Report id 730915
Category Antiseptic

Quality Substandard or Falsified

Source Unknown

Curation Manually curated

Snippet: Substandard hand sanitizers in the market threaten public health MyRepublica

Click here to see the Original Article

Table 7: Places for report 730915

Region Name	Country	Location	Latitude	Longitude
Southern Asia	Nepal	Kathmandu	27.70169	85.3206

Table 8: Drugs for report 730915

Medicine Name	Medicine Class	Action	ATC Code
ethanol	Other antiseptics	antiseptics and disinfec-	D08AX08
	and disinfectants	tants	
ethanol	Antidotes	all other therapeutic	V03AB16
		products	
ethanol	Nerve depressants	all other therapeutic	V03AZ01
		products	

Table 9: Other Stories

ID	Title	Link
744996	Govt bans nine brands of hand sanitizers with high amount of methanol	Link

Notes: KATHMANDU, Sept 17: The selling of substandard hand sanitizers is on rise in the Kathmandu Valley amid soaring demands and weak government monitoring, posing a serious

risk to the people's health.

Incidents of selling low-quality hand sanitizers have exposed the consumers' vulnerability to buying such products. A study carried out by the Nepal Academy of Science and Technology (NAST) two weeks ago also showed that around 45 percent of the hand sanitizers being sold in the local market are unfit for use.

The Department of Drug Administration (DDA) on Wednesday imposed a ban on sanitizers manufactured by four companies one each from China and India and two domestic manufacturers.

The regulator has invalidated Opacel Non Washing Antibacterial Solution from a Gwangjubased Chinese company, Pamacare Hand Sanitizer from RL Corp, India, Sasa Hand Sanitizer from Sampada Healthcare, Lalitpur, and Unicare Hand Sanitizer from Shreenath Herbal, Kathmandu. These products have been found to contain methanol, a type of poisonous alcoholic product, which is against the government-set standard for the product.

Just a few days ago, the DDA banned Instant Hand Sanitizer of Nepal Kayakalpa Udhyog, Bhaktapur. Likewise, Hygiene Soap and Chemical Pvt Ltd, Adhar Chemicals and Food Industry Pvt Ltd, Search Chem Cum Herbal Products and Suryamukhi Health Products also faced similar action from the government's regulatory body.

Handwashing and sanitizing have been identified among the best measures in curbing the spread of COVID-19. Following the pandemic, the government has enforced standards of alcohol-based instant hand sanitizer 2020', which has recognized sanitizers with at least 70 percent ethanol (ethyl alcohol) fit for use.

However, many companies are taking undue advantage of the spiked market demand for the product, and have been using poisonous alcohol in the disinfectant. Apart from this, the selling of fake sanitizers is also rampant in the poorly-regulated domestic market. Last June, the Metropolitan Police Crime Division seized a large amount of counterfeit sanitizers from Kathmandu-16, in which an Indian citizen was accused of producing the fake product.

6 Officials: 500,000 counterfeit N95 masks seized in Chicago

Publication date 2020-09-14

Create date 2020-09-18

Score 19.11

Report id 727707

Category Medical devices for disease prev

Quality Substandard or Falsified

Source

Curation Manually curated

Snippet: Officials: 500,000 counterfeit N95 masks seized in Chicago The San Diego Union-Tribune

Click here to see the Original Article

Table 10: Places for report 727707

Region Name	Country	Location	Latitude	Longitude
Americas	United States	Chicago O'Hare International Airport	41.97959	-87.90446

Table 11: Other Stories

ID	Title	Link
730371	Customs agents seize 500,000 counterfeit N95 masks	Link
	from China bound for New Jersey	
762117	Officials: \$3 million in counterfeit N95 masks from	Link
	China seized in Chicago	
728841	Counterfeit Masks Destined For Manalapan Seized By	Link
	U.S. Customs	
736521	Officials: 500,000 counterfeit N95 masks seized at	Link
	O'Hare	
728851	500,000 Counterfeit N95 Masks Being Shipped From	Link
	China To New Jersey Seized At O'Hare Airport	
729109	Coronavirus updates: 500,000 counterfeit N-95 masks	Link
	seized; COVID-19 was in US as early as December,	
	study says	
729123	Counterfeit N-95 masks confiscated: Half-million	Link
	masks confiscated at O'Hare, says U.S. Customs	
728106	Officials: \$3 million in counterfeit N95 masks from	Link
	China seized in Chicago	

Table 11: Other Stories(continued)

ID	Title	Link
764724	Officials: 500,000 counterfeit N95 masks seized in Chicago	Link
748102	Officials: \$3 million in counterfeit N95 masks from China seized	Link
733517	Customs seizes 500,000 faulty N95 masks in Chicago en route from China to New Jersey	Link
755810	Officials: 500,000 counterfeit N95 masks seized in Chicago	Link
727907	Half a million faulty' N-95 masks from China seized by US border agents, feds say	Link
731239	500,000 "faulty" N95 masks seized by CBP officers in Chicago	Link
737392	Officials: \$3 million in counterfeit N95 masks from China seized in Chicago	Link
729476	50000 Counterfeit N95 Masks Seized At O'Hare Airport	Link
761229	Half-million counterfeit N-95 masks confiscated at O'Hare: U.S. Customs	Link
735631	Federal officials seize 500,000 fake masks headed for Jersey	Link
730773	Border Patrol Seizes 500,000 Counterfeit N95 Masks in Chicago	Link
728985	500K Counterfeit N95 Masks Seized In Chicago — 1340 WJOL	Link
727714	Officials: 500000 counterfeit N95 masks seized in Chicago	Link
735405	500K Counterfeit N95 Masks Seized In Chicago — 1340 WJOL	Link
727995	Officials: 500,000 counterfeit N95 masks seized at O'Hare	Link
729289	Federal officials seize 500,000 fake masks headed for Jersey	Link
732874	Phony championship rings, fake N95 masks: What Customs agents are seizing at O'Hare	Link
729291	CBP Seizes 500,000 Counterfeit N95 Masks From China	Link
727763	Officials: 500,000 counterfeit N95 masks seized in Chicago — Coronavirus	Link
749011	Officials: \$3 million in counterfeit N95 masks from China seized in Chicago - WIAT	Link

Notes: CHICAGO About 500,000 counterfeit N95 respirator masks have been seized in Chicago by Customs and Border Protection officers, federal officials announced Monday. The shipment of masks from China was seized Sept. 10 at O'Hare International Airport, according to the

federal agency. It said the masks were headed to a company in Manalapan, New Jersey. The masks are used to prevent the spread of the COVID-19 virus.

Thirty were sent to a testing facility where it was determined that 10% of the respirators tested had a filter efficiency rating below 95%.

"These masks did not meet the safety standards outlined by the CDC, which puts the public at risk, jeopardizing the health and well-being of everyone," said Shane Campbell, port director for the Chicago area. Frontline workers, hospital officials and even the Food and Drug Administration say there is a shortage of the masks in the U.S. due to pressures on the medical supply chain.

7 176 hand sanitizers recalled after reports of blindness and hospitalizations, FDA reports

 Publication date
 2020-09-11

 Create date
 2020-09-18

Score 18.42

Report id 724196

Category

Antiseptic

Quality Substandard or Falsified

Source Unknown

Curation Manually curated

Snippet: 176 hand sanitizers recalled after reports of blindness and hospitalizations, FDA reports KSAT San Antonio

Click here to see the Original Article

Table 12: Places for report 724196

Region Name	Country	Location	Latitude	Longitude
Americas	United States	United States	39.76	-98.5

Table 13: Drugs for report 724196

Medicine Name	Medicine Class	Action	ATC Code
ethanol	Other antiseptics	antiseptics and disinfec-	D08AX08
	and disinfectants	tants	
ethanol	Antidotes	all other therapeutic	V03AB16
		products	
ethanol	Nerve depressants	all other therapeutic	V03AZ01
		products	
	Antiseptics	throat preparations	R02AA

Notes: SAN ANTONIO The U.S. Food and Drug Administration is warning consumers not to use 176 hand sanitizer products due to potential methanol contamination.

The FDA says the recalled hand sanitizer products are considered unsafe due to methanol contamination or because they contain "concerningly low levels of ethyl alcohol or isopropyl alcohol, which are active ingredients in hand sanitizer products."

The Centers for Disease Control and Prevention recommends that consumers use an alcohol-based hand sanitizer that contains at least 60 percent isopropyl or ethyl alcohol.

FDA officials said they were aware of reports of adverse events associated with the listed hand sanitizer products including adults and children who ingested products contaminated with methanol that led to blindness, hospitalizations and death.

New products were added to the list as recently as Tuesday with retail chains like Walmart and Costco having previously issued recalls for unknowingly selling the contaminated products.

The FDA is advising consumers not to use the recalled products because methanol - used in fuel, solvents and antifreeze - is poisonous to humans and substantial exposure could "result in nausea, vomiting, headache, blurred vision, permanent blindness, seizures, coma, permanent damage to the nervous system or death."

The list of recalled products, including details about the manufacturers, can be found on the FDA website. The investigation by the FDA into the use of methanol in hand sanitizers is ongoing.

8 More products added to FDA hand sanitizer recall list

Publication date 2020-09-28

Create date 2020-09-29

Score 18.32

Report id 745249

Category
Antiseptic

Quality Substandard or Falsified

Source Unknown

Curation Manually curated

Snippet: More products added to FDA hand sanitizer recall list WJTV

Click here to see the Original Article

Table 14: Places for report 745249

Region Name	Country	Location	Latitude	Longitude
Americas	United States	United States	39.76	-98.5

Table 15: Drugs for report 745249

Medicine Name	Medicine Class	Action	ATC Code
ethanol	Other antiseptics and disinfectants	antiseptics and disinfec-	D08AX08
	and disinfectants	tants	
ethanol	Antidotes		V03AB16
ethanol	Nerve depressants	all other therapeutic	V03AZ01
		products	
	Antiseptics		R02AA
propanol	Other antiseptics	antiseptics and disinfec-	D08AX03
	and disinfectants	tants	

Table 16: Other Stories

ID	Title	Link
745731	More products added to FDA hand sanitizer recall list - KTVE	Link
767544	More products added to FDA hand sanitizer recall list	Link

Table 16: Other Stories (continued)

ID	Title	Link
766037	Updated: More than 200 hand sanitizers listed on	Link
	FDA's do-not-use' list	
752039	More products added to FDA hand sanitizer recall list	Link

Notes: The Food and Drug Administration continues to add hand sanitizers to a list of products that should be avoided, with the list climbing to 196. Many of the recalled products contain methanol or 1-propanol, which are very dangerous. Only ethyl alcohol and isopropyl alcohol (also known as 2-propanol) are acceptable types of alcohol in hand sanitizer, according to the FDA. The complete list can be found on the FDA's site. FDA test results also showed some hand sanitizers had much lower levels of active ingredient than listed on the label. The CDC recommends alcohol-based hand sanitizers have at least 60% ethyl alcohol (sometimes listed as "alcohol" on the label). Other products were found with false or misleading claims on labels, including false claims that the brand prevents the spread of COVID-19 or protects you from viruses or bacteria for a certain period of time. Poison control officials warn of hand sanitizer that could be mistaken as children's food pouches Methanol, or methyl alcohol, is used to make rocket fuel and antifreeze and should never be rubbed on your skin or swallowed. Swallowing or drinking hand sanitizers contaminated with methanol can cause serious health problems, including permanent blindness, and death, according to the FDA. 1-Propanol or 1-propyl alcohol is used to make industrial solvents and can also be toxic when swallowed. Swallowing or drinking a hand sanitizer with 1-propanol can result in decreased breathing and heart rate, among other serious symptoms, and can lead to death, the FDA says. Symptoms of exposure can include confusion, decreased consciousness and slowed pulse and breathing. What should I look for in a hand sanitizer?

9 CDC: Beware of counterfeit N95 masks

Publication date 2020-09-02

Create date 2020-09-07

Score 17.89

Report id 712648

Category Medical devices for disease prev

Quality Substandard or Falsified

Source Unknown

Curation Manually curated

Snippet: CDC: Beware of counterfeit N95 masks Construction Dive

Click here to see the Original Article

Table 17: Places for report 712648

Region Name	Country	Location	Latitude	Longitude
Americas	United States	United States	39.76	-98.5

Notes: Dive Brief: - Recent federal government guidance cautions workers looking to protect themselves from hazards such as sand, silica dust or the coronavirus to carefully consider the source of their respiratory protection. - The National Institute for Occupational Safety and Health, which is part of the Centers for Disease Control and Prevention, says counterfeit respirators are being sold in the U.S. and that the models many of them made in China may not be capable of providing appropriate respiratory protection. - NIOSH has posted a list of dozens of suspect brands on its website as well as what to look for in approved face coverings. Dive Insight: Some of the brands listed as counterfeit include:

Valmy model VRN95 INSAFE DermaCare or Espomega with model numbers HY8710, HY8812 and HY8816 Intech Safety Pvt. Ltd. Safe Life model B130 and model B150 SAS model 8617A Some models claiming to be from Shining Star Electronic Technology NIOSH-approved respirators have an approval label on or within the packaging of the respirator and/or within the instructions containing one the following designations: N95, N99, N100, R95, R99, R100, P95, P99 or P100. Signs that a respirator may be counterfeit include:

No markings. NIOSH spelled incorrectly. The presence of decorative fabric or other decorative add-ons such as sequins. Claims approved for children. (NIOSH does not approve any type of respiratory protection for children.) Ear loops instead of headbands. Besides helping to mitigate the spread of the coronavirus, N95 masks provide protection from harmful airborne particles created when performing certain types of work such as sanding, drilling concrete, installing insulation and remediating lead paint.

While approved for use in construction, valved N95 masks are not suitable for COVID-19

mitigation as they can decrease the protection of those surrounding the wearer, recent studies have shown.

"Such a valve allows air to move from the wearer's mouth and nose through the mask without going through the main filter," one study said. "While this may make exhaling easier, at the same time, it may permit viruses to get on through to the other side."

The new guidance points to the fact that contractors should carefully consider where they buy their masks. Many of the problem masks come from online retailers, auction sites like eBay and third-party distribution networks. NIOSH lists warning signs that a retailer is suspect, such as offering a very low price compared to other outlets.

It is also important to see if the seller is marketing the same products over time or primarily selling trendy items, the institute said.

"Legitimate businesses and distributors typically sell what they know and stay consistent with their stock over time. A buyer should be able to discover this by looking into businesses' other products," it said, adding that buyers can gain insight on sellers on big online platforms such as Amazon by looking at reviews from buyers.

10 Smuggled medicines declared as PPEs foiled at MICP

Publication date 2020-09-22

Create date 2020-09-28

Score 17.00

Report id 737299

Category Medical devices for disease prev

Quality Diverted/Unregistered

Seaport

Curation Manually curated

Snippet: Smuggled medicines declared as PPEs foiled at MICP Manila Bulletin

Click here to see the Original Article

Table 18: Places for report 737299

Region Name	Country	Location	Latitude	Longitude
South-Eastern Asia	Philippines	Manila	14.6042	120.9822

Notes: A shipment declared as personal protective equipment but turned out to contain medicines was recently intercepted at the Manila International Container Port (MICP), the Bureau of Customs said. [...] Boxes of medicines and medicinal ointments were found in a shipment declared to contain personal protective gears and facemasks during an inspection on September 15.

The shipment with an estimated value of P50,000 came from Singapore and was consigned to F.E.R.N. Freight Enterprises, the bureau said. According to MICP District Collector Romeo Allan Rosales, the shipment did not have any import permits or clearances from pertinent government agencies, stressing that the importer attempted to bring in the undocumented medicines by taking advantage of the Customs' expedited process on shipments related to the coronavirus pandemic.

Rosales aired his concern on the possible adverse effects of using medicines which did not go through the necessary clearances set by the Food and Drug Administration (FDA). [...]

11 Five industries in Nepal to face action for producing substandard sanitizers

Publication date	2020-09-12
Create date	2020-09-18
Score	14.52
Report id	725135
Category	Antiseptic
Quality	Substandard
Source	Manufacturer
Curation	Manually curated

Snippet: Five industries in Nepal to face action for producing substandard sanitizers https://www.nepal24hours

Click here to see the Original Article

Table 19: Places for report 725135

Region Name	Country	Location	Latitude	Longitude
Southern Asia	Nepal	Kathmandu	27.70169	85.3206
Southern Asia	Nepal	Bhaktapur	27.67426	85.42647

Table 20: Other Stories

ID	Title	Link
725505	Five industries to face action for producing substandard sanitizers	Link

Notes: The Department of Drug Administration is all set to take action against five industries for producing non standard sanitizers, thereby posing threat to human health. N24 Staff Writer, KATHMANDU: The Department of Drug Administration is all set to take action against five industries for producing non standard sanitizers, thereby posing threat to human health.

Four such industries from Kathmandu and one from Bhaktapur district were blacklisted for producing sanitizer with the use of toxic chemical methanol. The Department said it would impose fine along with compensation of the damage caused by them and even close the industries for ever.

Instant hand sanitizer original' produced by Housing Shop and Chemical, advanced hand sanitizer' produced by Chemical Food and Industry, instant hand sanitizer: refreshing gel' by Search Chem Cum Herbal Product, Suryamukhi hand sanitizer' by Suryamukhi Herbal Product from Kathmandu, and by instant hand sanitizer' by Kayakalpa Industry from Bhaktapur were found

using poisonous methanol, said Department Director General Narayan Prasad Dhakal.

The Department had taken samples from the market and tested in its laboratory which revealed the fact that they were hazardous to human health. The people are appealed to not use these sanitizers.

12 Mumbai: Fake N95 masks flood market as COVID-19 cases spike

Publication date 2020-09-30

Create date 2020-10-07

Score 13.98

Report id 748680

Category Medical devices for disease prev

Quality Falsified

Source Manufacturer

Curation Manually curated

Snippet: Mumbai: Fake N95 masks flood market as COVID-19 cases spike Mid-day

Click here to see the Original Article

Table 21: Places for report 748680

Region Name	Country	Location	Latitude	Longitude
Southern Asia	India	Mumbai	19.07283	72.88261
Southern Asia	India	Delhi	28.65195	77.23149
Southern Asia	India	State of Karnataka	14.66667	75.83333
Southern Asia	India	State of Mahrshtra	19.5	76

Table 22: Other Stories

ID	Title	Link
760687	The epidemic of fake branded masks — India Business	Link
	Law Journal	

Notes: These masks are even used by frontline workers and they are at greater risk as the masks are not made as per standard specifications. [...] However, the prices of N95 masks have been spiking for quite some time now with one mask being sold for anything around Rs 150-200. This has led to the rise in fake mask manufacture with the logos of top N95 mask manufacturing companies.[...] According to Mumbai Mirror, Delhi police have seized fake N95 masks and filed FIRs under the Copyrights Act and Indian Penal Code (IPC). Companies that manufacture N95 masks have filed cases against fake mask manufacturers in Maharashtra and Karnataka in July and August. [...] "There have been many reports of fake N95 masks flooding the market. Since our company has a recognisable brand, they use our logos. In the Delhi case, even our packaging and dyes were found. We have filed four FIR and complaints in the last two months.

These masks are being sold as real N95 masks and the level of duplicity is very serious," said Mahesh Kudav, the owner of Venus, one of biggest N95 mask manufacturing company. "The fake N95 masks are a big risk since they give a false sense of security. These masks are even used by frontline workers and they are at greater risk as the masks are not made as per standard specifications. Now we have started seminars for small mask manufacturers so they can improve quality," Kudav said.

13 185 hand sanitizers recalled after reports of blindness and hospitalizations, FDA report

Publication date 2020-09-18

Create date 2020-09-23

Score 13.64

Report id 732787

Category
Antiseptic

Quality Substandard or Falsified

Source Unknown

Curation Manually curated

Snippet: 185 hand sanitizers recalled after reports of blindness and hospitalizations, FDA report KSAT San Antonio

Click here to see the Original Article

Table 23: Places for report 732787

Region Name	Country	Location	Latitude	Longitude
Americas	United States	United States	39.76	-98.5

Notes: The U.S. Food and Drug Administration is warning consumers not to use 185 hand sanitizer products due to them potentially being unsafe or ineffective.

The FDA says the recalled hand sanitizer products are considered unsafe due to methanol contamination or because they contain "concerningly low levels of ethyl alcohol or isopropyl alcohol, which are active ingredients in hand sanitizer products." [...] FDA officials said they were aware of reports of adverse events associated with the listed hand sanitizer products including adults and children who ingested products contaminated with methanol that led to blindness, hospitalizations and death. New products were added to the list as recently as Tuesday with retail chains like Walmart and Costco having previously issued recalls for unknowingly selling the contaminated products. [...]

14 Anti-bacterial gel prohibited in US continues to be sold in Mexico

Publication date 2020-09-10

Create date 2020-09-11

Score 13.50

Report id 723274

Category Medical devices for disease prev

Quality Substandard

Source Unknown

Curation Manually curated

Snippet: Anti-bacterial gel prohibited in US continues to be sold in Mexico Mexico News Daily

Click here to see the Original Article

Table 24: Places for report 723274

Region Name	Country	Location	Latitude	Longitude
Americas	Mexico	Mexico	23	-102

Notes: Hand sanitizers that were banned in the United States because they were found to contain methanol are still available for purchase in Mexico, prompting concerns that people using the gel could be slowly poisoning themselves.

The news agency Bloomberg reported that four people in the United States died and three others partially lost their sight after drinking hand sanitizers this year.

The incidents prompted the U.S. Food and Drug Administration (FDA) to conduct a testing campaign that found methanol in anti-bacterial gel that was made in Mexico. A total of 37 Mexican companies were prohibited from exporting their hand sanitizers north of the border and almost half that number voluntarily recalled their products. However, at least some are still selling their potentially toxic sanitizers in Mexico. [...]

Thirty-three of 137 hand sanitizers banned by the FDA were produced by a México state-based company called 4E Global. The FDA found methanol in two of its anti-bacterial gels but banned all of its sanitizers because they were likely made at the same facility as the contaminated ones.

"Some of our series of Blumen Hand sanitizers were found to contain methanol," 4E Global says on its United States website.

"Out of an abundance of caution, we decided to recall all lots due to potential contamination." The company's Spanish language website doesn't mention methanol or any product recalls, Bloomberg said.

Among the other brands that were found to contain methanol were Jaloma, V-KLEAN, Herbacil

Hand Sanitizer and Saniderm.

15 Health Canada issues recall of counterfeit hand sanitizer

Publication date 2020-10-01 Create date 2020-10-07 Score 13.50 Report id 749766 Category Antiseptic Falsified Quality Source Unknown Curation Manually curated

Snippet: Health Canada issues recall of counterfeit hand sanitizer CTV News

Click here to see the Original Article

Table 25: Places for report 749766

Region Name	Country	Location	Latitude	Longitude
Americas	Canada	Canada	60.10867	-113.64258

Table 26: Other Stories

ID	Title	Link
761565	Health Canada issues recall of counterfeit hand sanitizer	Link

Notes: Health Canada says it has announced a recall after discovering a company selling a counterfeit version of one of the hand sanitizers on its approved list.

In a release Thursday, the agency says they had become aware that the distributor Northern National Sales Inc. was selling a fake version of Zytec Germ Buster Hand Sanitizer.

Health Canada says it worked with Emback Spraytech Inc., the company behind the authorized product, in order to make sure the counterfeit version was not one of theirs. s the demand for hand sanitizer grew early on in the pandemic, Health Canada released a list of approved hand sanitizers that met the government's requirement for sale in Canada, in order to ensure that consumers would not be taken in by products claiming to be hand sanitizer that did not match up to regulations.

Zytec Germ Buster Hand Sanitizer is authorized for sale in Canada, but officials say the counterfeit version claiming this name is not. Health Canada states that they had reached out to the distributor of the counterfeit and instructed them to recall the product. [...] Health Canada says both versions of the product carry the same NPN, or Natural Product Number, 80015625,

and the same lot number, 3329733126.

However, the real product has a colour label, and the version with those two numbers only comes in 3.78 litres, while the counterfeit version has a black and white label and uses those numbers on a one-litre bottle.

Health Canada says anyone who possess the counterfeit version should stop using it immediately, and contact health-care practitioners if you have used it and are feeling concerned about your health.

Northern National Sales Inc. has confirmed that they are no longer selling the product, according to Health Canada.

16 ACC files case against 7 over N95 mask scam

Publication date 2020-09-29

Create date 2020-10-08

Score 13.01

Report id 746401

Category Medical devices for disease prev

Quality Falsified

Source Not applicable

Curation Manually curated

Snippet: ACC files case against 7 over N95 mask scam Dhaka Tribune

Click here to see the Original Article

Table 27: Places for report 746401

Region Name	Country	Location	Latitude	Longitude
Southern Asia	Bangladesh	Dhaka	23.7104	90.40744

Table 28: Other Stories

ID	Title	Link
757088	HC directs two N95 mask scam accused to surrender	Link
753065	N95 mask scam: JMI Chairman Abdur Razzak ar-	Link
	rested in case filed against him, 6 CMSD staffers	
746185	N95 mask scam: ACC arrests JMI chief Abdur Razzak	Link
746448	N95 Mask Scam: JMI chief Abdur Razzak on 5-day	Link
	remand following arrest by ACC	
754427	N95 mask scam: ACC imposes travel ban on 6 govt	Link
	officials, JMI chief	

Notes: The Anti-Corruption Commission (ACC) on Tuesday filed a case against six officials of the health department and the chairman of JMI Hospital Requisite Manufacturing Ltd (JHRML) Md Abdur Razzaq on charges of supplying and receiving fake N95 masks. [...] Including the JHRML chairman, the seven benefited through misusing their authority. They were responsible for supplying and receiving 20,610 fake N95 masks which were later distributed to 10 healthcare institutes, said an ACC statement. Additional information Report ID: 757088 (https://www.newagebd.net/article/118355/hc-directs-two-n95-mask-scam-accused-to-surrender)The High Court on Wednesday directed two health officials accused in fake N95

mask manufacturing and supplying case to surrender to the lower court concerned seeking bail within three weeks.

The bench of Justice M Enayetur Rahim and Justice Md Mostafizur Rahman issued the directive after rejecting the bail petitions filed by Central Medical Store Depot's former deputy director Zakir Hossain, now superintendent of Cox's Bazar General Hospital, and DGHS' senior storekeeper Mohammad Yusuf Fakir.

On September 29, ACC deputy director Md Nurul Huda filed the case against JMI Hospital Requisite Manufacturing Ltd Chairman Md Abdur Razzak and six current and former officials of the Central Medical Store Depot, including Zakir and Yusuf, on charge of supplying fake N95 masks to CMSD.

The ACC arrested Razzak on September 29 and he is now in its custody for five days.

Four other accused who were not arrested or surrendered to the court are CMSD's assistant director (storage and distribution) Shahjahan Sarkar, chief coordinator and desk officer Mohammad Ziaul Haque (now attached to DGHS), desk officer with additional responsibilities of the store Sabbir Ahmed (now medical officer of Dewanganj Upazila Health Complex in Jamalpur) and store officer (acting) Kabir Ahmed (now on post-retirement leave).

17 Up to 70% of KN95 masks imported from China don't meet filtration standards, study says

Publication date 2020-09-22

Create date 2020-10-13

Score 12.20

Report id 761005

Category Medical devices for disease prev

Quality Substandard

Source Manufacturer

Curation Manually curated

Snippet: Up to 70% of KN95 masks imported from China don't meet filtration standards, study says USA TODAY

Click here to see the Original Article

Table 29: Places for report 761005

Region Name	Country	Location	Latitude	Longitude
Americas	United States	United States	39.76	-98.5

Notes: A shortage of N95 masks forced hospitals to find alternatives to protect health care workers tending COVID-19 patients. Cue the KN95 mask. As its name advertises, the KN95 mask is meant to filter out 95% of aerosol particles. However, nonprofit patient safety organization ECRI issued a high-priority hazard alert against these masks after an analysis found that up to 70% of KN95 masks imported from China did not meet these filtration standards. U.S. hospitals purchased hundreds of thousands of KN95 masks produced in China over the past six months. [...] ECRI tested nearly 200 masks from 15 different manufacturer models purchased by some of the largest health systems in the country. Schabacker said there was not only variability among the different brands but also inconsistencies among masks made by the same manufacturer. [...] In April, the Food and Drug Administration issued an umbrella emergency use authorization for masks that are manufactured in China and not approved by the National Institutes of Occupational Safety and Health (NIOSH). The agency reissued the order in June.

Besides the filtration concerns, public health experts criticized KN95 masks for their inability to create a tight seal on someone's face. N95 masks have head and neck straps; KN95s have ear loops. [...] Schabacker said the ECRI analysis controlled for the KN95's inferior ear loops by taking them off and creating a seal when testing the models. This means that even if the KN95 mask had head and neck straps, it still wouldn't protect health care workers to the degree that an N95 mask would.

18 NAFDAC confiscates N350,000 worth of fake hand sanitisers in Bauchi

Publication date 2020-09-24

Create date 2020-09-28

Score 11.17

Report id 741664

Category Medical devices for disease prev

Quality Falsified

Source Unspecified outlet

Curation Manually curated

Snippet: NAFDAC confiscates N350,000 worth of fake hand sanitisers in Bauchi Naija247news

Click here to see the Original Article

Table 30: Places for report 741664

Region Name	Country	Location	Latitude	Longitude
Western Africa	Nigeria	Bauchi	10.31032	9.84388

Table 31: Other Stories

ID	Title	Link
740744	NAFDAC seizes N350,000 worth of fake hand sanitis-	Link
	ers in Bauchi	

Notes: Bauchi, Sept. 24, 2020 The National Agency for Food and Drugs Administration and Control (NAFDAC), Bauchi State Office, says it has seized cartons of fake hand sanitizers worth N350,000 in some super markets and drug retail outlets in the state.

The State Coordinator, Mr Mohammed Muazu, told newsmen in Bauchi on Thursday the the items were confiscated following a raid on shops carried out three days ago.

He said the exercise was sequel to a directive from the Enforcement Directorate of the Agency. Muazu said that of the 13 brands of the fake sanitizers,11 were manufactured in Kano state while two were produced in Bauchi state.

He said that the Agency had commenced investigation to trace the manufacturers, saying the monitoring exercise would continue, and that any culprit apprehended would face the full wrath of the law.

The Coordinator urged the public to be mindful of NAFDAC and Batch Numbers, Manufac-

turing and Expiry dates of food, drugs and medical consumable.

"The general public should understand that quality of hand sanitizers not registered by NAF-DAC cannot be guranteed, and the aim will not be achieved",he said. (NAN)

19 Brokers Peddle Fake Medical Gloves Amid Coronavirus Shortages

Publication date 2020-09-15

Create date 2020-10-08

Score 9.88

Report id 728784

Category Medical devices for disease prev

Quality Falsified

Source Distributor/Wholesaler

Curation Manually curated

Snippet: Brokers Peddle Fake Medical Gloves Amid Coronavirus Shortages The Wall Street Journal

Click here to see the Original Article

Table 32: Places for report 728784

Region Name	Country	Location	Latitude	Longitude
Americas	United States	United States	39.76	-98.5

Table 33: Other Stories

ID	Title	Link
767952	Brokers Peddle Fake Medical Gloves Amid Coronavirus Shortages	Link

Notes: Brokers are peddling counterfeit medical gloves as a shortage of this critical commodity has tripled prices during the pandemic and pinched front-line and other workers as schools and businesses reopen. In recent weeks, companies employing front-line workers have bought fake versions of "nitrile," or synthetic rubber gloves, sold in boxes labeled "examination grade," posing potential health risks, according to glove distributors and manufacturers

20 Police bust factories: Used medical gloves resold and painkillers sold as herbal medicine

Publication date 2020-09-11

Create date 2020-09-11

Score 9.71

Report id 723710

Category Herbal medicine, Medical devices for disease prev

Quality Diverted/Unregistered

Source Unknown

Curation Manually curated

Snippet: Police bust factories: Used medical gloves resold and painkillers sold as herbal medicine The Thaiger

Click here to see the Original Article

Table 34: Places for report 723710

Region Name	Country	Location	Latitude	Longitude
South-Eastern Asia	Thailand	Kingdom of Thailand	15.5	101

Notes: Police busted 2 factories. The first allegedly produced medicine illegally, selling medicines containing steroids and painkillers as "herbal medicine." The other was allegedly repackaging used medical gloves, boxing them up and making them look good as new. [...] (*) In the herbal medicine bust, police seized 400,000 packages of what police say is "fake" herbal medicine under the brand name "Jindamanee." Instead of herbs meant to relieve pain, the medicines have steroids and painkillers, police say. [...]

(*) In the used rubber glove bust, Police searched Pantyod Health Planet's factory in Bangkok's Nong Khaem district. Police say they seized over 900,000 pairs of used medical gloves worth nearly 10 million baht. Apparently, the used gloves were imported into Thailand and then repackaged in Bangkok. Along with being used, the gloves don't meet government standards to be used in the medical field. The company's president Pantayod Akamornrapong was arrested for violating the Medical Device Act. The factory also isn't registered. Police say the president faces a year in prison and a fine up to 300,000 baht. [...]

21 Substandard masks delay govt's free mask scheme

Publication date 2020-09-04

Create date 2020-09-07

Score 6.28

Report id 715991

Category Medical devices for disease prev

Quality Substandard

Source Manufacturer

Curation Manually curated

Snippet: Substandard masks delay govt's free mask scheme Times of India

Click here to see the Original Article

Table 35: Places for report 715991

Region Name	Country	Location	Latitude	Longitude
Southern Asia	India	Coimbatore	11.00555	76.96612

Notes: Coimbatore: The state government's free mask distribution scheme is yet to be launched in the district as a whopping number of masks it received from the contractor, who won the tender, was of substandard quality. The district has rejected 5.85 lakh masks that were supplied by the contractor so far. The government plan is to distribute the free masks through ration shops to the card holders. An official with the office of district supply officer said, "We have been receiving masks in batches since August. After receiving them, they were sent to the handlooms department for quality check. The masks that did not satisfy the parameters prescribed by the state government were rejected." The district had received around 12 lakh masks till Augustend and 5.85 lakh of them were rejected during the quality check, the official, who requested anonymity, said. He said another batch of five lakh masks had arrived on Thursday and they were sent for quality check. "To implement the free mask scheme in the district, we need 62 lakh masks." Pointing out that the state government's plan was to distribute the free masks in the city corporation limits on top priority, the official said a minimum of 25 lakh masks were required for the same going by the number of ration card holders. Otherwise, he said, they might not be able to send masks to all the ration shops and distribute the same without any gaps. The district has only 6.15 lakh masks in stock. As per the scheme, two masks would be distributed per person in a family. According to a source with the district administration, once the masks are sent to the handloom department, one sample per 5,000 masks would be selected on random basis and sent to a private textile laboratory for quality check. Among other factors, the size of masks and length of tapes would also be looked into. A source with the South India Textile Research Association, which check the samples for quality, said, "At the laboratory, we would test the samples to identify its fabric count - one of the factors calculated to determine the

thickness of the sample - and its fibre content to check whether it's 100% cotton or not. Both the tests are done separately for the weft and warp yarn - basic components used in weaving to turn yarn into fabric - of the samples." As per the government guidelines, the masks should be made of 100% cotton fabric and the count of both the weft and warp yarn should be 2/40. "Once the testing is completed, we would send back the samples along with the test results to the handloom department, which would then take the final call on whether to approve or reject the product," the source said.

22 Taipei man detained for alleged production, sale of counterfeit masks

Publication date 2020-09-11

Create date 2020-09-11

Score 6.28

Report id 723919

Category Medical devices for disease prev

Quality Falsified

Source Manufacturer

Curation Manually curated

Snippet: Taipei man detained for alleged production, sale of counterfeit masks Focus Taiwan News Channel

Click here to see the Original Article

Table 36: Places for report 723919

Region Name	Country	Location	Latitude	Longitude
Eastern Asia	Taiwan	Taipei	25.04776	121.53185

Table 37: Other Stories

ID	Title	Link
762625	Man suspected of making fake medical-grade masks	Link
724265	Man suspected of making fake medical-grade masks	Link

Notes: Taichung, Sept. 11 (CNA) A Taipei man has been detained for allegedly setting up an underground face mask factory and using it to supply pharmacies with masks labeled as those of a major domestic manufacturer, prosecutors said Friday.

The suspect, surnamed Huang (), is alleged to have sold some 750,000 masks falsely labeled as having been produced by Taiwan Pro-Level Papers International Co. to pharmacies in central Taiwan, earning NT\$5 million (US\$170,738) in the process.

Taiwan Pro-Level Papers International Co. is a member of the National Face Mask Team that produces medical grade masks for both the domestic market and for export.

According to the Taichung District Prosecutors Office, the fraud was uncovered after a member of the public reported that a Taichung pharmacy was selling what appeared to be counterfeit medical grade masks.

In a subsequent investigation, the authorities found that Huang had ordered several boxes of medical grade masks from Taiwan Pro-Level Papers in February and March of this year.

In May, he allegedly purchased a mask assembly line and around 1 ton of raw materials, and began producing non-medical grade masks in a rented factory space in New Taipei's Xizhi District.

To pass the masks off as genuine, he hired a local printing company to reproduce the packaging used by Taiwan Pro-Level Papers, and forged the medical device license number that appears on the packaging of legitimate medical grade masks, the prosecutors said.

On Tuesday, the authorities raided Huang's residence and factory, seizing three mask assembly machines, 400,000 masks and raw materials sufficient to produce an additional 2.5-3 million masks, the prosecutors said. [...] Meanwhile, in response to the growing number of mask-related fraud cases in recent weeks, the Taiwan High Prosecutors Office said Friday that it has instructed all offices under its jurisdiction to prioritize investigations into the false labeling of masks' grade quality and country of origin.

From Sept. 17, Taiwan will require all locally made surgical face masks to carry special imprints of the acronyms "MD" (medical device) and "MIT" (made in Taiwan) to discourage potential counterfeiters.

It will also begin requiring government approval for the import of both medical and non-medical grade face masks, and mandate that importers report their distribution of the masks on a weekly basis, with effect from Sept. 16.

23 Taiwan company caught importing Chinese masks for ration program

Publication date 2020-09-03

Create date 2020-09-07

Score 6.26

Report id 714826

Category Medical devices for disease prev

Quality Diverted/Unregistered

Source Manufacturer

Curation Manually curated

Snippet: Taiwan company caught importing Chinese masks for ration program Taiwan News

Click here to see the Original Article

Table 38: Places for report 714826

Region Name	Country	Location	Latitude	Longitude
Eastern Asia	Taiwan	Taiwan	24	121

Table 39: Other Stories

ID	Title	Link
715533	Tsai and Su denounce mask supplier	Link

Notes: Taiwan firm busted for repackaging Chinese masks for government's domestically produced mask program. TAIPEI (Taiwan News) A Taiwan company on Thursday (Sept. 4) was ordered by the government to cease operations after it was found to have imported over 3 million non-medical grade masks from China in August and repurposed them for Taiwan's government real-name mask rationing system.

On Wednesday (Sept. 2), pharmacies in New Taipei reported that after receiving their latest shipment of what should have been Taiwan-made masks for the government's real-name rationing system, they also received masks with labeling in the simplified Chinese script used in China, indicating they were made by a company in Anhui Province. Chen Chao-yuan (), chairman of the New Taipei City Pharmacists Association (NTPA), estimated that about one-third of the city's 1,100 pharmacies, more than 300, received the counterfeit masks. [...] On a Facebook post uploaded on Thursday, Democratic Progressive Party (DPP) Legislator Lin Shu-fen () revealed the Taiwan company Carry Mask (() in August imported 3.37 million masks made in China, relabeling and repackaging them as government-rationed and domestically-manufactured

face mask supplies. Lin then posted a photo of the masks labeled by Carry as "Made in Taiwan," which she had purchased, and wondered if she had the "s*** luck" of having received a batch of bogus Chinese masks. [...] Many of the masks have the words "Carry mask" printed on them to disguise their Chinese origin. In March of this year, customs caught out Carry importing a batch of masks from China labeled as "Made in Taiwan," reported Liberty Times. The owner of Carry mask, Lin Ming-chin (), spoke to the media on Thursday evening and said that he was no longer proud of being part of the National Face Mask Team because the government was putting too much pressure on local suppliers who, he suggested, have little choice but to outsource manufacturing to China. As for the masks made in Anhui, he admitted that he purchased the raw materials and commissioned a Chinese company to manufacture the masks.

However, he claimed the masks have a filtration percentage of 99.8 percent, which he claimed was much higher than most other companies. Lin apologized for causing consumer panic but insisted, "I'm really not a black heart factory!

24 Lagos shuts 21 illegal Pharmacies

Publication date 2020-09-23

Create date 2020-09-28

Score 6.16

Report id 739297

Category Not applicable

Quality Not Directly Relevant

Source Unlicensed outlets

Curation Manually curated

Snippet: Lagos shuts 21 illegal Pharmacies P.M. News

Click here to see the Original Article

Table 40: Places for report 739297

Region Name	Country	Location	Latitude	Longitude
Western Africa	Nigeria	Alakuko	6.67986	3.25928
Western Africa	Nigeria	Ifako-Ijaiye Local Gov-	6.66503	3.30279
		ernment Area		
Western Africa	Nigeria	Alimosho	6.5889	3.24852
Western Africa	Nigeria	Agege	6.63937	3.30757
Western Africa	Nigeria	Ijaiye	7.3614	3.71312
Western Africa	Nigeria	Lagos	6.45407	3.39467
Western Africa	Nigeria	Abule-Egba	6.64144	3.29323
Western Africa	Nigeria	Agbado Oke-Odo Lo-	6.64751	3.26816
		cal Council Develop-		
		ment Area		
Western Africa	Nigeria	Ajegunle	6.45197	3.33115
Western Africa	Nigeria	Ologogoro	6.59719	3.84022

Table 41: Other Stories

ID	Title	Link
739741	LASG Shuts 21 Illegal, Substandard Pharmacies And	Link
	Patent Medicine Stores	
739836	Lagos Shuts 21 Illegal, Substandard Pharmacies,	Link
	Patent Medicine Stores	
739582	Lagos shuts 21 substandard pharmacy stores	Link

Notes: The Lagos State Government has shutdown 21 pharmacies, patent medicine shops and unlicensed premises at different parts of the state. The affected pharmacies and others were shut at Alakuko, Ajegunle, Ologogoro, Ijaiye, Abule-Egba, Agbado and Agege in Alimosho, Ifako-Ijaiye and Agege Local Government areas of Lagos by the Lagos State Taskforce on Counterfeit, Fake Drugs and Unwholesome Processed Foods for offences bordering on illegal operation and operating beyond scope of practice. [...] Abayomi explained that the affected premises were sealed for offences including; operating without license, engaging unqualified persons to man and dispense drugs to unsuspecting citizens, operating beyond scope through sale of ethical products, displaying and storing drugs in unconducive environments which compromises the potency of the drugs there by rendering them ineffective, among others. [...] "This closure is thus part of the government's renewed efforts to sanitize the drug distribution system and curb proliferation of fake drugs in the State," Backley said. [...] The enforcement and compliance raid by the State Task force on Counterfeit, Fake Drugs and Unwholesome Processed Foods was carried out in collaboration with the National Agency for Food Drug Administration and Control (NAFDAC), Pharmacists' Council of Nigeria (PCN), Pharmaceutical Society of Nigeria (PSN), Federal Taskforce on Fake Drugs and the Police Officers from Environmental and Special Offences Unit (Task Force) of Lagos Police Command.

25 Supplier detained in Changhua for allegedly selling counterfeit masks

Publication date 2020-09-08

Create date 2020-09-09

Score 6.10

Report id 719567

Category Medical devices for disease prev

Quality Falsified

Source Distributor/Wholesaler

Curation Manually curated

Snippet: Supplier detained in Changhua for allegedly selling counterfeit masks Focus Taiwan News Channel

Click here to see the Original Article

Table 42: Places for report 719567

Region Name	Country	Location	Latitude	Longitude
Eastern Asia	Taiwan	Nantou	23.91566	120.66387
Eastern Asia	Taiwan	Changhua	23.95361	120.49083

Table 43: Other Stories

ID	Title	Link
724341	610000 fraudulent surgical masks circulate in central	Link
	Taiwan	
740554	Taichung supplier detained for allegedly selling coun-	Link
	terfeit masks	

Notes: The owner of a company in Changhua County has been detained for allegedly supplying pharmacies with surgical masks from unknown sources, prosecutors said Tuesday.

The company is accused of procuring 610,000 non-medical grade masks from an unknown source, falsely labeling them to look as if they had been made by Hung Wei Medical Consumable Co. of Taiwan, and supplying them to pharmacies in Nantou County, according to prosecutors.

Hung Wei Medical is one of the manufacturers on the National Face Mask Team that produce Taiwan-made masks for the domestic market and for export.

The owner of the supply company that allegedly falsely labeled the masks to look like Hung Wei Medical products was summoned by Nantou prosecutors Monday for questioning, along

with three other suspects, and a Nantou court on Tuesday granted a request for him to be held in detention.

The investigation was launched after a consumer reported on Aug. 2 that the masks purchased at a Nantou pharmacy appeared to be counterfeit, according to the Nantou District Prosecutors Office. Prosecutors said the company, owned by the suspect surnamed Liu (), had deliberately branded the masks with a name that was very similar in Chinese to Hung Wei Medical, which would lead buyers to think the masks were produced by the National Face Mask Team.

On Aug. 20, authorities seized about 400 counterfeit masks at two pharmacies in Nantou, and another 11,600 at the home of one of the pharmacy owners, according to prosecutors.

Investigators later traced the products to Liu's company and seized 203,800 masks at four separate locations operated by the company, prosecutors said, adding that they have not yet been able to determine the origin of the masks.

Liu is being held incommunicado to prevent him from colluding with accomplices and destroying evidence, prosecutors said. He could face charges of fraud, document forgery and violation of the Pharmaceutical Affairs Act, they said. [Covid-19]

26 Company sells 4 million fake 'Made in Taiwan' masks from China

Publication date 2020-09-10

Create date 2020-09-10

Score 6.10

Report id 722442

Category Medical devices for disease prev

Quality Falsified

Source Distributor/Wholesaler

Curation Manually curated

Snippet: Company sells 4 million fake 'Made in Taiwan' masks from China Taiwan News

Click here to see the Original Article

Table 44: Places for report 722442

Region Name	Country	Location	Latitude	Longitude
Eastern Asia	Taiwan	Taiwan	24	121

Table 45: Other Stories

ID	Title	Link
722505	Another Taiwanese manufacturer accused of selling	Link
	counterfeit masks	

Notes: Amid its campaign to crack down on the counterfeit masks pouring in from China, the Ministry of Economic Affairs (MOEA) has caught a Taiwanese company selling 4 million fake "Made in Taiwan" masks.

On Sept. 4, "Carry Mask" () was ordered to cease operations after it was found to have imported over 3 million non-medical grade masks from China in August and repurposed them for Taiwan's government real-name mask rationing system. Investigators have since found that several companies from the "National Face Mask Team" have been cutting corners by importing masks from China and the MOEA has begun to widen its search for other violators.

When reviewing customs data on imports, the MOEA found that Haw Ping Co., Ltd. () had imported 7.18 million masks from China in August, reported SET News. After launching an investigation, the MOEA found that the company had 3 million masks in storage, while it had already sold more than 4 million to Taiwanese consumers.

The head of Haw Ping admitted to prosecutors that his company and was released on bail on

Wednesday evening (Sept. 9). Based on a preliminary investigation, Haw Ping imported 3D non-medical masks from China, then added the company's logo.

27 Taipei drugstore chain caught selling rationed masks made in Philippines

Publication date 2020-09-16

Create date 2020-09-18

Score 6.08

Report id 729679

Category Medical devices for disease prev

Quality Falsified

Source Private pharmacy

Curation Manually curated

Snippet: Taipei drugstore chain caught selling rationed masks made in Philippines Taiwan News

Click here to see the Original Article

Table 46: Places for report 729679

Region Name	Country	Location	Latitude	Longitude
Eastern Asia	Taiwan	Taipei	25.04776	121.53185

Notes: AIPEI (Taiwan News) Taiwanese drugstore chain Great Tree Pharmacy () on Wednesday (Sept. 16) admitted that employees at one branch had sold masks made in the Philippines to customers who believed they were part of the Taiwanese government's real-name mask rationing system.

In response to reports that the pharmacy chain had been passing off Philippine-made masks as official government-rationed ones, the firm on Wednesday blamed its employees for selling the wrong masks due to "personal negligence," reported Liberty Times. The company said it has provided the relevant information to the authorities and that the branch involved has temporarily suspended all operations and will cooperate with officials in investigating the case. On Aug. 31, a female teacher used her National Health Insurance card to purchase five packs of what she believed to be government-rationed masks at a Great Tree Pharmacy on Xiyuan Road in Taipei. When she returned home, she found that instead of the label "Made in Taiwan," 36 masks in four of the packages were labeled "Med Tecs," reported UDN. She began to suspect that they could be counterfeit. When she contacted Med Tecs, she was told that the masks were made in the Philippines. According to Great Tree Pharmacy, the Philippine-made masks are medical grade and have been approved by Taiwan's Food and Drug Administration. The company claimed that it had not purchased the masks directly from Med Tecs () but through qualified channels. The drugstore chain denied it had intentionally harmed the interests of consumers for the sake of profit. The company has reiterated its apology to the public and pledged to strengthen management and supervision in the future.

28 Morocco Arrests Man for Selling Fake COVID-19 Face Masks in Casablanca

Publication date 2020-09-21

Create date 2020-09-28

Score 6.02

Report id 736630

Category Medical devices for disease prev

Quality Falsified

Source Clandestine laboratory

Curation Manually curated

Snippet: Morocco Arrests Man for Selling Fake COVID-19 Face Masks in Casablanca Morocco World News

Click here to see the Original Article

Table 47: Places for report 736630

Region Name	Country	Location	Latitude	Longitude
Northern Africa	Morocco	Casablanca	33.58831	-7.61138

Notes: The man bought the masks from an industrial zone in Casablanca, and put them in boxes bearing the brand of a company that sells medical face masks. Rabat Morocco's police arrested on Monday a 32-year-old man in Casablanca for his alleged involvement in a case of fraud and for selling fake face masks for COVID-19.

The suspect bought the masks from a workshop in the Moulay Rachid industrial zone and put them in boxes bearing the brand of companies that sell "this type of medical equipment," the General Directorate of National Security (DGSN) said.

Police arrested the suspect after receiving a complaint that a company filed against him.

Searches carried out as part of an investigation enabled police to seize 121,600 fake protective masks.

Police put the suspect in custody for further investigation to determine the circumstances of the case

Morocco launched local production of face masks at textile factories to ensure sufficient supply, and to alleviate economic pressures on industrial units given the COVID-19 pandemic's repercussions.

The country also started exporting locally-produced face masks to several European countries, including France.

29 'Crack down on sellers of sub-standard masks,' NTF urges DTI

Publication date 2020-09-08

Create date 2020-09-09

Score 5.88

Report id 719408

Category Medical devices for disease prev

Quality Substandard or Falsified

Source Unknown

Curation Manually curated

Snippet: 'Crack down on sellers of sub-standard masks,' NTF urges DTI Manila Bulletin

Click here to see the Original Article

Table 48: Places for report 719408

Region Name	Country	Location	Latitude	Longitude
South-Eastern	Philippines	Republic of the Philip-	13	122
Asia		pines		

Notes: The National Task Force (NTF) Against COVID-19 is urging the Department of Trade and Industry (DTI) to run after sellers of imported face masks that are of low quality. NTF Secretary Carlito Galvez Jr. said he received reports about the presence of imported face masks in the market which did not pass the country's health standards but are still being sold at a much cheaper price.

"We will talk to DTI. I have been informed of this," Galvez admitted when asked about the matter. After learning about the rampant selling of sub-standard face masks, Galvez said he made an initial coordination with DTI Secretary Ramon Lopez tolook into the matter.

"Sabi niya, we will regulate yong ano kasi ang face mask na hindi maganda will give a fall sense of security (According to [Lopez], we will regulate it because sub-standard face masks will give a false sense of security)," the chief implementer said. [...]

30 Warning! Counterfeit hand sanitisers being sold on the market

Publication date 2020 - 09 - 08Create date 2020-09-09 Score 5.44Report id 719716 Category Antiseptic Quality Falsified Source Unknown Curation Manually curated

Snippet: Warning! Counterfeit hand sanitisers being sold on the market BVI News Online

Click here to see the Original Article

Table 49: Places for report 719716

Region Name	Country		Location	Latitude	Longitude
Americas	Virgin (British)	Islands	British Virgin Islands	18.5	-64.5

Table 50: Drugs for report 719716

Medicine Name	Medicine Class	Action	ATC Code
	Antiseptics	throat preparations	R02AA
ethanol	Other antiseptics	antiseptics and disinfec-	D08AX08
	and disinfectants	tants	
ethanol	Antidotes	all other therapeutic	V03AB16
	products		
ethanol	Nerve depressants	all other therapeutic	V03AZ01
		products	
propanol	Other antiseptics	antiseptics and disinfec-	D08AX03
	and disinfectants	tants	

Table 51: Other Stories

ID	Title	Link
721194	BVI Health Ministry Warns Fake Hand Sanitizers	Link
	'Sold On Market', Deadly To Children And Pets.	

Table 51: Other Stories(continued)

ID	Title	Link
721255	BVI Health Ministry Alerts Public To Counterfeit	Link
	Hand Sanitisers	
738185	BVI Health Ministry Alerts Public To Counterfeit	Link
	Hand Sanitisers	

Notes: The Ministry of Health has issued a warning for residents of the British Virgin Islands to beware of counterfeit hand sanitisers that could be fatal to users.

A late-night media release from the ministry on Monday, September 7 said these fake sanitisers are being "sold on the market".

Residents are, therefore, advised to look out for these fake hand sanitisers whose active ingredients include a toxic gel called methanol/methyl alcohol and 1-propanol/propyl alcohol.

31 Surge In Illegal Drugs And COVID-19 Counterfeits During Pandemic Shipments

Publication date 2020-09-24

Create date 2020-09-28

Score 4.94

Report id 740485

Category Medical device for screening/dia, Medical devices for disease prev, Psychoactive substance

Quality Falsified

Source Unknown

Curation Manually curated

Snippet: Surge In Illegal Drugs And COVID-19 Counterfeits During Pandemic Shipments CBS Chicago

Click here to see the Original Article

Table 52: Places for report 740485

Region Name	Country	Location	Latitude	Longitude
Americas	United States	Chicago	41.85003	-87.65005

Table 53: Other Stories

ID	Title	Link
746326	Surge In Illegal Drugs And COVID-19 Counterfeits During Pandemic Shipments	Link

Notes: CHICAGO (CBS) An explosion of illegal drugs and an increasing cache of counterfeits are flowing through one of the busiest mail facilities in the country, right here in Chicago. [...] Between March and August of last year, CBP agents in the Chicago Field Office seized more than 8,800 pounds of narcotics.

Between March and August of this year? That number exploded to more than 21,000 pounds. [...] Among phonies found? Prescription drugs, designer drugs, designer brands like Nike and Cartier. You name it. But a new addition to 2020 seizures is pandemic products.

There were COVID 19 test cards, rapid kits, and detection kits in just a day's worth of the phony COVID 19 products coming through Chicago's International Mail Facility.

Campbell explained the risk of some of the fake tests for people who wittingly or unwittingly order them: "They have a false negative but they may or may not be actually positive. But

they're using a bad test in the hopes that it's going to tell them what they want to hear."[...] Unfortunately, there's no sniff test for fake COVID test or counterfeit PPE.

CBP has to rely on a system of radiation screening, x-ray screening and physical inspections. It's been a grueling workflow during the pandemic. [...] The Chicago Field Office receives about 57 million shipments every year. Campbell said the majority of counterfeits come from China.

32 CDSCO flags 22 Drug Samples As Not Of Standard Quality

Publication date 2020-09-14

Create date 2020-09-18

Score 4.63

Report id 727310

Category Antipsychotic, Antiseptic, Antispasmodic, Vitamin, Anxiolytic, Antiviral others, Anti-inflammatory medicine, Antibiotic

Quality Substandard

Source Unknown

Curation Manually curated

Snippet: CDSCO flags 22 Drug Samples As Not Of Standard Quality Medical Dialogues

Click here to see the Original Article

Table 54: Places for report 727310

Region Name	Country	Location	Latitude	Longitude
Southern Asia	India	Republic of India	22	79

Table 55: Drugs for report 727310

Medicine Name	Medicine Class	Action	ATC Code
aciclovir	Antivirals	chemotherapeutics for	D06BB03
		topical use	
aciclovir	Nucleosides and	direct acting antivirals	J05AB01
	nucleotides excl.		
	reverse transcrip-		
	tase inhibitors		
aciclovir	Antivirals	antiinfectives	S01AD03
	Antiseptics	throat preparations	R02AA
clidinium and psycholeptics	Synthetic anti-	antispasmodics in	A03CA02
	cholinergic agents	combination with	
	in combination	psycholeptics	
	with psycholep-		
	tics		
folic acid	Folic acid and	vitamin b12 and folic	B03BB01
	derivatives	acid	
			A11
	Vitamins	i.v. solution additives	B05XC

Table 55: Drugs for report 727310(continued)

Medicine Name	Medicine Class	Action	ATC Code
diclofenac	Other dermato- logicals	other dermatological preparations	D11AX18
diclofenac	Acetic acid derivatives and related substances	antiinflammatory and antirheumatic prod- ucts, non-steroids	M01AB05
diclofenac	Antiinflammatory preparations, non-steroids for topical use	topical products for joint and muscular pain	M02AA15
diclofenac	Antiinflammatory agents, non-steroids	antiinflammatory agents	S01BC03
prazosin	Alpha- adrenoreceptor antagonists	antiadrenergic agents, peripherally acting	C02CA01
amoxicillin	Penicillins with extended spectrum	beta-lactam antibacterials, penicillins	J01CA04
		vitamin b12 and folic acid	B03B
magnesium hydroxide	Magnesium compounds	antacids	A02AA04
magnesium hydroxide	Other urologicals	urologicals	G04BX01

Notes: New Delhi: The apex drug regulatory body, Central Drugs Standard Control Organization (CDSCO) has flagged 22 drug samples as 'Not of Standard Quality' after they failed to qualify a random drug sample test for the month of August. These drug samples included popular formulations and brands like Folic Acid Tablets I.P. 5mg, Diclofenac gel B.P. 1% w/w, Hypodermic Syringe 2ml, Herpivir-800 Tablets, RYAAL, Vibpure Hand Sanitizer, Ulcon Tablets, Allyn Instant Dry Hand Rub, Amzeclav-625 Tablets, and others.

This came after analysis and test conducted by the CDSCO, Drugs Control Departments, on 843 drug samples. Out of this, 821 samples were found of Standard quality while 22 of them were declared as Not of Standard Quality (NSQ). A few of the causes why the drug samples tested failed included Sterility, Assay, Dissolution, Description & Particulate Matter, Uniformity of weight, Assay of Isopropyl Alcohol, Assay of Ethyl Alcohol, and so on.

The samples were collected by the Drugs Control Department of Gujarat, Assam, Govt .of N.C.T of Delhi, Himachal Pradesh, and Srinagar Further CDSCO Ahmedabad, Ghaziabad, and Kolkata also picked up samples. Tests were conducted in three laboratories namely CDL Kolkata, RDTL Chandigarh, RDTL Guwahati. List of Drugs, Medical Devices and Cosmetics declared as Not of Standard Quality/Spurious/Adulterated/Misbranded, for the Month of August 2020

33 Big haul of fake goods seized by Japan customs

Publication date 2020-09-12

Create date 2020-09-18

Score 3.48

Report id 725140

Category Medical devices for disease prev

Quality Falsified

Source Unknown

Curation Manually curated

Snippet: Big haul of fake goods seized by Japan customs NHK WORLD

Click here to see the Original Article

Table 56: Places for report 725140

Region Name	Country	Location	Latitude	Longitude
Eastern Asia	Japan	Japan	35.68536	139.75309

Notes: Japanese customs officers intercepted more than 15,000 counterfeit products headed into the country in the first half of this year. That's the biggest haul of pirated goods in three years. The Finance Ministry says imports of fake brand goods were halted in 15,344 cases between January and June. That's up 18.7 percent year on year.

86 percent of the counterfeits were from China.

By category, fake brand clothing accounted for 4,663 cases. Wallets and purses followed at 4,626, and watches at 2,342.

There were also copies of Japanese-brand face masks and fake medals for the Tokyo Olympics. The ministry attributes the spike partly to an increase in people shopping online as they stay home amid the coronavirus pandemic.

34 Mass Bacterial Infection from Chinese Pharmaceutical Company Casts Doubts on COVID Vaccine

Publication date 2020-09-17

Create date 2020-09-18

Score 2.58

Report id 732310

Category Vaccine, Veterinary medicines

Quality Substandard

Source Manufacturer

Curation Manually curated

Snippet: Mass Bacterial Infection from Chinese Pharmaceutical Company Casts Doubts on COVID Vaccine American Council on Science and Health

Click here to see the Original Article

Table 57: Places for report 732310

Region Name	Country	Location	Latitude	Longitude
Eastern Asia	China	People's Republic of China	35	105

Table 58: Drugs for report 732310

Medicine Name	Medicine Class	Action	ATC Code
	Brucellosis vac- cines	bacterial vaccines	J07AD

Notes: In China, brucellosis is more common and outbreaks still occur. However, the most recent brucellosis outbreak, which has infected at least 3,245 people, surely is a first: The source of the infection was not contaminated food but a pharmaceutical factory. How on earth could that happen?

Well, there's more than one way to get brucellosis. Consuming raw or unpasteurized food is one way. Another is to touch animal products contaminated with the bacteria, which can enter the body through breaks in the skin. Yet another route is inhalation. While this is mostly a threat to those who come into close contact with animals or animal products, like slaughterhouse workers, infection via inhalation can occur if the bacteria are aerosolized. And that's exactly what happened in China.

CNN has reported that a pharmaceutical company that was manufacturing brucellosis vaccines

for animals was using expired disinfectants. Waste gas emitted from the factory contained live Brucella, which then wafted its way into the city of Lanzhou, infecting thousands of people.

Who Wants a Chinese COVID Vaccine?

This news doesn't come at a particularly good time for China, which has been blamed for causing and then covering up the ongoing coronavirus pandemic. Like in several other countries, Chinese companies are working to produce a vaccine against coronavirus. One company, called CanSinoBIO, is testing their vaccine in soldiers. Lucky them!

Not to be jingoistic, but there's a reason why things like this don't happen in the United States, Europe, Japan, or other advanced nations: A culture of safety and regulation when it comes to industries that have the power to cure or kill its customers. China simply does not have that. Yet, the U.S. (and many other countries) use Chinese ingredients in the pharmaceutical drugs that we manufacture. As I wrote for USA Today, this is a substantial threat to national security and public health.

Incidents like the mass infection described above should further stiffen our resolve to deal strongly with China, forcing them to adopt standards that are acceptable to Americans and citizens of other advanced nations. Until then, China poses an unnecessary risk to global health. As a case-in-point, who among you would actually sign up for a Chinese COVID vaccine?

35 Darknet Dealers are Selling COVID-19 Test Kits for Thousands of Dollars

Publication date 2020-09-11

Create date 2020-09-11

Score 2.29

Report id 723812

Category Medical device for screening/dia, Medical devices for disease prev, Vaccine, Anti-malarial

Quality Diverted/Unregistered

Source Website(s)

Curation Manually curated

Snippet: Darknet Dealers are Selling COVID-19 Test Kits for Thousands of Dollars VICE

Click here to see the Original Article

Table 59: Places for report 723812

Region Name	Country	Location	Latitude	Longitude
Americas	United States	United States	39.76	-98.5
		Earth	0	0

Table 60: Drugs for report 723812

Medicine Name	Medicine Class	Action	ATC Code
			J07
hydroxychloroquine	Aminoquinolines	antimalarials	P01BA02

Notes: VICE News spoke to one vendor who claims he's made more than \$1.4 million USD selling kits to hospitals and geriatric homes around the world. [...] Acting on a tip-off from connections in China and Hong Kong, the US-based businessman pulled together a network of like-minded entrepreneurs who bought thousands of COVID-19 IgM/IgG Rapid Tests directly from a handful of factories in Germany and Korea. [...] Speaking to VICE News over Wickr, Jason (not his real name) revealed that he's sold 8,000 COVID-19 testing kits on the dark web to dateeach one going for \$180 USD a piece. Half of those were snapped up by medical centres in Italy and the United States; 1,000 went to a geriatric home in an unspecified location; while another 3,000 were bought out by a single individual, who Jason suspects was acting on behalf of a mystery government or hospital. [...] Jason isn't the only illegal operator who's found a way to profiteer during the pandemic. VICE News found dozens of online dealers peddling

2020-10-22 59

spurious coronavirus "vaccines", along with sheets of hydroxychloroquine pills and the blood of recovered COVID-19 patients for nearly \$16,000 USD per liter. [...] "Many of these vendors take advantage of the panic," he said. "There are some who promise to sell all kinds of remedies which are probably fake, [while] others sell protective gear like masks and hand santizers [amid] a worldwide shortage [and] we have strong reason to believe it's of low quality. We even know of some groups who sell used facemasks." [...] Any type of protective gear that hasn't been approved for use by the relevant authorities is not safe for use, says Maimon, who strongly advises against relying on any type of health-related commodity that has been acquired on the dark web.

"Of course there are a lot of fake drugs and commodities out there as well," he adds, "so consumers need to be vigilant regarding the manufacturers and the vendors they purchase from."

If Jason can be taken at his word, though, he's in the business of hoarding and selling coronavirus test kits for reasons that are more altruistic than financial suggesting that he's the one who doesn't have time for anyone not taking the COVID crisis seriously.

36 Cyprus role in 21 country operation targeting counterfeits

Publication date 2020-09-28

Create date 2020-09-29

Score 1.75

Report id 745185

Category Medical devices for disease prev

Quality Substandard or Falsified

Source Website(s)

Curation Manually curated

Snippet: Cyprus role in 21 country operation targeting counterfeits Cyprus Mail

Click here to see the Original Article

Table 61: Places for report 745185

Region Name	Country	Location	Latitude	Longitude
Europe	Italy	Repubblica Italiana	42.83333	12.83333
Europe	Portugal	Portuguese Republic	39.6945	-8.13057
Europe	Spain	Kingdom of Spain	40	-4
Europe	Cyprus	Republic of Cyprus	35	33
Europe	Belgium	Kingdom of Belgium	50.75	4.5
Europe	Ireland	Ireland	53	-8
Europe	Greece	Hellenic Republic	39	22
Europe	Romania	România	46	25

Notes: Nearly 28 million counterfeit and illegal goods, including 27 million facemasks, were seized as part of Europe-wide operation Aphrodite involving 21 countries, including Cyprus, Europol has announced.

The eight-month operation targeting counterfeit goods trafficking was co-led by the Italian Finance Corps (Guardia di Finanza) and the Irish National Police (An Garda Síochána) with support from Europol, and lasted from December 2019 to July 2020.

During this period, law enforcement authorities tracked online sales of a large variety of counterfeit items, culminating in checks in warehouses, shops and marketplaces in Belgium, Cyprus, Greece, Ireland, Italy, Portugal, Romania and Spain. The operation led to 123 social media accounts and 36 websites selling counterfeit products taken down. [...] Moreover, the Covid-19 outbreak led the authorities to adapt the initial scope of the operation to focus on issues triggered by the pandemic. As a result, counterfeit and illegal medical equipment was also seized, including 27 million medical facemasks by the Italian Finance Corps (Guarda di Finanza).. Digital platforms, such as websites, social media and instant messaging services are abused by

2020-10-22 61

criminal groups to sell often harmful counterfeit products. Illegal vendors advertise counterfeit goods with pictures and prices of fake products on social media. They also use hidden links in posts on social media to redirect users to marketplaces located outside of the EU. Offers for counterfeit goods also grew on e-commerce platforms and subsequently, their share of the market increased.

Criminals invite unsuspecting buyers to pay with prepaid cards, by wire transfer or other forms of electronic payment and web-based services as the goods are delivered through legal couriers. The COVID-19 pandemic intensified the sale of counterfeit goods on the physical market too.

Annex

7.4 COVID-19 medicines

Medicine Quality Monitoring Globe

October 22, 2020



This is a summary of the information available in the Medicine Quality Monitoring Globe for the search terms selected between the dates selected. For more information on the terminology used, caveats and the work of the medicine quality group please see the information at: https://www.iddo.org/medicine-quality

Non-Curated reports are those that have been automatically flagged as relevant by the system but have not been manually curated by the curators.

We would be grateful for any feedback on this summary and for the details of any reports that we may have missed.

Search

"tranilast" OR "interleukin-2" OR "zilucoplan" OR "AT-001" OR "nitazoxanide" OR "baloxavir" OR "doxycycline" OR "interleukin-7" OR "Kineret" OR "leronlimab" OR "ritonavir" OR "bevacizumab" OR "lactoferrin" OR "losartan" OR "UTTR1147A" OR "Caesalpinia spinosa" OR "remedesivir" OR "nitrogen monoxide" OR "lanadelumab" OR "tirofiban" OR "huaier extract" OR "corbistadine" OR "atorvastatin" OR "tozumab" OR "NP-120" OR "nitrite" OR "captopril" OR "merimepodib" OR "GLS-1200" OR "aescinate" OR "tranexamic" OR "colchicine" OR "procalcitonin" OR "SNDX-6352" OR "sirukumab" OR "monalizumab" OR "carriomycin" OR "ramipril" OR "tofacitinib" OR "budesonide" OR "bemiparin" OR "dipyridamole" OR "T89" OR "levamisole" OR "fingolimod" OR "atovaquone" OR "aspirin" OR "enoxaparin" OR "pyridostigmine" OR "TJM2" OR "poractant" OR "isotretinoin" OR "levilimab" OR "degarelix" OR "LY3819253" OR "telmisartan" OR "masitinib" OR "lenzilumab" OR "avdoralimab" OR "duvelisib" OR "bicalutamide" OR "Ilaris" OR "atlizumab" OR "Ifenprodil" OR "RBT-9" OR "deferoxamine" OR "canakinumab" OR "LB1148" OR "desferrioxamine" OR "chlorpromazine" OR "selinexor" OR "vitamin D2" OR "DAS181" OR "vitamin D3" OR "Clopidogrel" OR "tetrandrine" OR "amoxicillin" OR "zanubrutinib" OR "nitric Oxide" OR "chlorine dioxide" OR "AVM0703" OR "cobicistat" OR "olokizumab" OR "ABX464" OR "lucinactant" OR "galidesivir" OR

"thalidomide" OR "TXA127" OR "conestat" OR "corticosteroid" OR "vazegepant" OR "escin" OR "octagam" OR "pacritinib" OR "ribavirin" OR "ambrisentan" OR "baricitinib" OR "imatinib" OR "CD24Fc" OR "thymosin" OR "DFV890" OR "retinoic acid" OR "sitagliptin" OR "sevoflurane" OR "prednisone" OR "amoxicillin/clavulanic acid" OR "TJM-2" OR "ulinastatin" OR "oestrogen" OR "leflunomide" OR "virazole" OR "naltrexone" OR "abidor" OR "niclosamide" OR "ATYR1923" OR "Olumiant" OR "Alinia" OR "argatroban" OR "Leukine" OR "methotrexate" OR "xiyanping" OR "peginterferon" OR "artemisinin" OR "ibrutinib" OR "pembrolizumab" OR "aescin" OR "CERC-002" OR "fludase" OR "isoflurane" OR "dornase" OR "XPro1595" OR "telemedicine" OR "immunoglobulin" OR "nafamostat" OR "clarithromycin" OR "bromhexine" OR "Xpovio" OR "ebastine" OR "amoxicillin/clavulanate" OR "PD-1 mAb" OR "opaganib" OR "oseltamivir" OR "melatonin" OR "favipiravir" OR "mefloquine" OR "huaier granule" OR "bismuth" OR "ifenprodil" OR "famotidine" OR "tenofovir" OR "secukinumab" OR "AMY-101" OR "umifenovir" OR "EDP1815" OR "pinavir" OR "tocilizumab" OR "coamoxiclav" OR "LAU-7b" OR "hydroxychloroquine" OR "triazavirine" OR "cholecalciferol" OR "RTB101" OR "zinc" OR "fondaparinux" OR "oxytocin" OR "gimsilumab" OR "suramin" OR "rhG-CSF" OR "ciclesonide" OR "desferoxamine" OR "azithromycin" OR "calciferol" OR "TD-0903" OR "clazakizumab" OR "BCX4430" OR "pirfenidone" OR "adamumab" OR "etoposide" OR "RPH-104" OR "defibrotide" OR "AT-527" OR "prazosin" OR "triazavirin" OR "alpha lipoic" OR "almitrine" OR "ergocalciferol" OR "dihydroartemisinin" OR "vitamin c" OR "melphalan" OR "dapagliflozin" OR "TMJ2" OR "25-hydroxyvitamin D3" OR "formoterol" OR "isoprinosine" OR "IMU-838" OR "indomethacin" OR "tridecactide" OR "chloroquine" OR "naproxen" OR "fluoxetine" OR "Kevzara" OR "valsartan" OR "ruxolitinib" OR "sargramostim" OR "estradiol" OR "cyclosporine" OR "silymarin" OR "linagliptin" OR "vitamin D" OR "methylprednisolone" OR "simvastatin" OR "fluvoxamine" OR "alteplase" OR "sildenafil" OR "mavrilimumab" OR "anakinra" OR "isoquercetin" OR "ozanimod" OR "ketamine" OR "mepolizumab" OR "camostat" OR "acetylsalicylic" OR "darunavir" OR "novaferon" OR "YinHu Qing-Wen" OR "camrelizumab" OR "acalabrutinib" OR "Cosentyx" OR "estrogen" OR "dexmedetomidine" OR "Dantonic" OR "nivolumab" OR "aviptadil" OR "PUL-042" OR "rivaroxaban" OR "diammonium" OR "adalimumab" OR "apremilast" OR "nitrogen oxide" OR "BMS-986253" OR "polyinosinic-polycytidylic" OR "farpiravir" OR "siltuximab" OR "interleukin 2" OR "montelukast" OR "jakotinib" OR "nintedanib" OR "garadacimab" OR "ASC09" OR "emtricitabine" OR "Pulmozyme" OR "hydrogen peroxide" OR "verapamil" OR "sarilumab" OR "azvudine" OR "BLD-2660" OR "ravulizumab" OR "hydrocortisone" OR "tinzaparin" OR "omalizumab" OR "EIDD-2801" OR "MSTT1041A" OR "Tybost" OR "Actemra" OR "dociparastat" OR "ascorbic acid" OR "abidole" OR "omeprazole" OR "MAS825" OR "progesterone" OR "eculizumab" OR "povidon-iodine" OR "ivermectin" OR "APL-9" OR "colomycin" OR "danoprevir" OR "amiodarone" OR "sirolimus" OR "lenalidomide" OR "resveratrol" OR "ixekizumab" OR "dexamethasone" OR "acetylcysteine" OR "TJ003234" OR "LY3127804" OR "iloprost" OR "tacrolimus" OR "dalteparin" OR "astegolimab" OR "interferon" OR "Xue-Bi-Jing" OR "plitidepsin" OR "metenkefalin" OR "azoximer" OR "lopinavir" OR "carrimycin" OR "gs-441542"

Start date	2020-09-01
End date	2020-09-30
Language	en
Number of Reports	16

1 Mumbai Crime Watch: Delhi man held for selling fake anticoronavirus drug

Publication date 2020-09-30

Create date 2020-10-01

Score 15.78

Report id 748338

Category Immunosuppressant

Quality Falsified

Source Clandestine laboratory

Curation Manually curated

Snippet: Mumbai Crime Watch: Delhi man held for selling fake anti-coronavirus drug Free Press Journal

Click here to see the Original Article

Table 1: Places for report 748338

Region Name	Country	Location	Latitude	Longitude
Southern Asia	India	Mumbai	19.07283	72.88261

Table 2: Drugs for report 748338

Medicine Name	Medicine Class	Action	ATC Code
tocilizumab	Interleukin in-	immunosuppressants	L04AC07
	hibitors		

Table 3: Other Stories

ID	Title	Link
754987	Mumbai Crime Watch: Delhi man held for selling fake	Link
	anti-coronavirus drug	
750129	Mumbai Crime: Chemist arrested for selling fake	Link
	COVID-19 treatment drug	
748667	Man arrested for selling fake Covid treatment drug	Link

Notes: The city crime branch has arrested a 40-year-old medical store owner from Delhi for allegedly making a copy of anti-coronavirus drug Tocilizumab. The accused identified as Ajay

Shamlal Nasa has created a fake Tocilizumab by adding asthma medicines. He charged Rs1 lakh per vial, which cost him not more than Rs 20 per vial.

On August 3, City Crime Branch Unit 9 arrested a person named Azam Nasif Khan (30) for alleged black marketing of anti-COVID drugs. Fifteen vials of Tocilizumab were recovered from him. "We sent the samples of seized drugs to its main manufacturer in Switzerland to check whether it is original or not. They informed us that it's not their medicine," said Nandakumar Gopale, senior inspector of Crime Branch Unit 9.

During interrogation Khan told the crime branch that he had procured the drug from Nasa, a resident of Govindpuri in New Delhi. A crime branch team then left for Delhi and arrested Nasa.

During his interrogation, Nasa told the investigators that in July he bought an original drug from Gurugram for Rs 58,000 and decided to make a copy of it. He then gave orders of exact similar empty vials of the original drug and also made fake labels and boxes of the original drug. Investigators were shocked when Nasa revealed that he added injections of Dexona and Deriphyllin with distilled water into the vials. Dexona and Deriphyllin cost Rs 5 respectively. He allegedly sold the fake vials for Rs 1 lakh to needy patients, said an official.

"During the probe it was revealed that the accused had given orders of 3000 vials. We have slapped IPC sections of adulteration of drugs (274), sale of adulterated drugs (275) and causing hurt by means of poison (328), in the main case," added Gopale. Nasa was produced before court on Wednesday which sent him to police custody till October 3.

2 Extrapharma.com - 607931 - 09/02/2020 - 2020-09-10

Publication date 2020-09-10

Create date 2020-09-11

Score 15.68

Report id 723098

Category Antiviral others, Antibiotic

Quality Diverted/Unregistered

 \mathbf{Source} Website(s)

Curation Manually curated

Snippet: Unapproved and Misbranded Products Related to Coronavirus Disease 2019 (COVID-19)

Click here to see the Original Article

Table 4: Places for report 723098

Region Name	Country	Location	Latitude	Longitude
Americas	United States	United States	39.76	-98.5

Table 5: Drugs for report 723098

Medicine Name	Medicine Class	Action	ATC Code
amoxicillin	Penicillins with extended spec- trum	beta-lactam antibacterials, penicillins	J01CA04
azithromycin	Macrolides	macrolides, lin- cosamides and strep- togramins	J01FA10
azithromycin	Antibiotics	antiinfectives	S01AA26

Notes: This is to advise you that the United States (U.S.) Food and Drug Administration (FDA) reviewed your website at the Internet address www.extrapharma.com on August 10, 2020. The FDA has observed that your website offers drug products for sale in the U.S. and that these products are intended to mitigate, prevent, treat, diagnose, or cure COVID191 and a variety of other diseases, such as bacterial infections of the ear, skin, soft tissue, and airways, as well as sexuallytransmitted bacterial infections such as "chlamydia, nonspecific urethritis, ureaplasma urealyticum and mycoplasma genitalium." Based on our review, these products are unapproved new drugs sold in violation of section 505(a) of the Federal Food, Drug, and

2020-10-22 5

Cosmetic Act (FD&C Act), 21 U.S.C. 355(a). Furthermore, these products are misbranded drugs under section 502 of the FD&C Act, 21 U.S.C. 352. The introduction or delivery for introduction of these products into interstate commerce is prohibited under sections 301(a) and (d) of the FD&C Act, 21 U.S.C. 331(a) and(d). We note that there are numerous unapproved and misbranded drugs offered for sale on your website. The violative products listed in this letter are intended to be examples that are illustrative of the violations we observed on your website. [...] For example, www.extrapharma.com offers Arbidol and states that "ARBIDOL blocks viruses and helps to eliminate them" and that "Arbidol has proven activity against influenza A and B viruses (including "swine" and "avian"), parainfluenza, coronavirus, as well as other major causative agents of respiratory infections. . . . " There are no approved drug applications pursuant to section 505 of the FD&C Act in effect for the Arbidol offered by www.extrapharma.com. In addition, no drug has yet been approved by the FDA for use in the prevention, diagnosis, treatment, mitigation, or cure of COVID19.4

Your website, www.extrapharma.com, also offers amoxicillin, marketed as "Amoxil", under the heading of "ANTIBIOTICS." While there are FDAapproved versions of amoxicillin on the market in the U.S., there are no approved drug applications pursuant to section 505 of the FD&C Act in effect for the amoxicillin or "Amoxil" offered by www.extrapharma.com. FDAapproved amoxicillin is labeled for treatment of infections due to susceptible strains of designated microorganisms and is only available by prescription.

Another example of an unapproved new drug offered by www.extrapharma.com is azithromycin, marketed as "Zithromax," which your website states "is highly effective in treating infections in the skin, ears, soft tissue. . . . " Additionally your website states, "Azithromycin is used to treat bacterial infections such as chlamydia, nonspecific urethritis, ureaplasma urealyticum and mycoplasma genitalium." While there are FDAapproved versions of azithromycin on the market in the U.S., there are no approved drug applications pursuant to section 505 of the FD&C Act in effect for the azithromycin or "Zithromax" offered by www.extrapharma.com. FDAapproved azithromycin is labeled for use in treating mild to moderate infections caused by susceptible strains of designated microorganisms in specific conditions and is only available by prescription.

3 Medication-house.com - 607751 - 09/02/2020 - 2020-09-10

Publication date 2020-09-10

Create date 2020-09-11

Score 15.58

Report id 723165

Category Antiviral others, Antibiotic

Quality Diverted/Unregistered

 \mathbf{Source} Website(s)

Curation Manually curated

Snippet: Unapproved and Misbranded Products Related to Coronavirus Disease 2019 (COVID-19)

Click here to see the Original Article

Table 6: Places for report 723165

Region Name	Country	Location	Latitude	Longitude
Americas	United States	United States	39.76	-98.5

Table 7: Drugs for report 723165

Medicine Name	Medicine Class	Action	ATC Code
amoxicillin	Penicillins with extended spec- trum	beta-lactam antibacterials, penicillins	J01CA04
azithromycin	Macrolides	macrolides, lin- cosamides and strep- togramins	J01FA10
azithromycin	Antibiotics	antiinfectives	S01AA26

Notes: This is to advise you that the United States (U.S.) Food and Drug Administration (FDA) reviewed your website at the Internet address www.medicationhouse.com on August 10, 2020. The FDA has observed that your website offers drug products for sale in the U.S. and that these products are intended to mitigate, prevent, treat, diagnose, or cure COVID19 and a variety of other diseases such as bacterial infections, including infections of the respiratory tract, genitourinary system, gastrointestinal tract, and skin and soft tissues. Based on our review, these products are unapproved new drugs sold in violation of section 505(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. 355(a). Furthermore, these products

are misbranded drugs under section 502 of the FD&C Act, 21 U.S.C. 352. The introduction or delivery for introduction of these products into interstate commerce is prohibited under sections 301(a) and (d) of the FD&C Act, 21 U.S.C. 331(a) and (d). We note that there are numerous unapproved and misbranded drugs offered for sale on your website. The violative products listed in this letter are intended to be examples that are illustrative of the violations we observed on your website. [...] For example, www.medicationhouse.com offers Arbidol and states that "Arbidol inhibits the activity of influenza A and B viruses, as well as the coronavirus associated with severe respiratory syndrome. The active substance stimulates the humoral and cellular immune responses, which helps to increase resistance to viral infections." There are no approved drug applications pursuant to section 505 of the FD&C Act in effect for the Arbidol offered by www.medicationhouse.com. In addition, no drug has yet been approved by the FDA for use in the prevention, diagnosis, treatment, mitigation, or cure of COVID19.4

Your website, www.medicationhouse.com, also offers amoxicillin, described as an "antibacterial, bactericidal, acidresistant, broadspectrum agent from the group of semisynthetic penicillins." Furthermore, according to your website, "[Amoxicillin is] [a]ctive against grampositive bacteria. . . ." While there are FDAapproved versions of amoxicillin on the market in the U.S., there are no approved drug applications pursuant to section 505 of the FD&C Act in effect for the amoxicillin offered by www.medicationhouse.com. FDAapproved amoxicillin is labeled for treatment of infections due to susceptible strains of designated microorganisms and is only available by prescription.

Another example of an unapproved new drug offered by www.medicationhouse.com is azithromycin, described on your website as an "organic substance from the group of macrolides, a subclass of azalides." Furthermore, your websites states, "The antibiotic has a broad spectrum of activity and is active against various types of bacteria gramnegative, grampositive, aerobic and anaerobic." While there are FDAapproved versions of azithromycin on the market in the U.S., there are no approved drug applications pursuant to section 505 of the FD&C Act in effect for the azithromycin offered by www.medicationhouse.com. FDAapproved azithromycin is labeled for the treatment of mild to moderate infections caused by susceptible strains of designated microorganisms and is only available by prescription.

4 Remdesivir batch withdrawn due to inferior quality: Maharashtra government

Publication date 2020-09-23

Create date 2020-10-09

Score 7.80

Report id 739155

Category Antiviral others

Quality Substandard

Source Manufacturer

Curation Manually curated

Snippet: Remdesivir batch withdrawn due to inferior quality: Maharashtra government ETHealthworld.com

Click here to see the Original Article

Table 8: Places for report 739155

Region Name	Country	Location	Latitude	Longitude
Southern Asia	India	State of Mahrshtra	19.5	76

Table 9: Other Stories

ID	Title	Link
740307	Maha Govt recalls batch of COVID drug Remdesivir	Link
	over quality issue	

Notes: A batch of Remdesivir for treatment of COVID-19 patients has been withdrawn in view of "sub-standard quality" of the medicine, Maharashtra Health Minister Rajesh Tope said on Wednesday. He told reporters that the move caused a short-term shortage of the drug in the state. "A batch of Remdesivir medicine was found to be (of) substandard (quality) and has been withdrawn, resulting into a short term shortage in its supply," he said. Seeking to allay concerns over shortage of Remdesivir, the minister said the government held talks with pharma companies and ensured sufficient supply of the medicine for COVID-19 patients. [Covid-19 treatment, Remedesivir]

5 CDSCO flags 22 Drug Samples As Not Of Standard Quality

Publication date 2020-09-14

Create date 2020-09-18

Score 7.80

Report id 727310

Category Antipsychotic, Antiseptic, Antispasmodic, Vitamin, Anxiolytic, Antiviral others, Anti-inflammatory medicine, Antibiotic

Quality Substandard

Source Unknown

Curation Manually curated

Snippet: CDSCO flags 22 Drug Samples As Not Of Standard Quality Medical Dialogues

Click here to see the Original Article

Table 10: Places for report 727310

Region Name	Country	Location	Latitude	Longitude
Southern Asia	India	Republic of India	22	79

Table 11: Drugs for report 727310

Medicine Name	Medicine Class	Action	ATC Code
aciclovir	Antivirals	chemotherapeutics for	D06BB03
		topical use	
aciclovir	Nucleosides and	direct acting antivirals	J05AB01
	nucleotides excl.		
	reverse transcrip-		
	tase inhibitors		
aciclovir	Antivirals	antiinfectives	S01AD03
	Antiseptics	throat preparations	R02AA
clidinium and psycholeptics	Synthetic anti-	antispasmodics in	A03CA02
	cholinergic agents	combination with	
	in combination	psycholeptics	
	with psycholep-		
	tics		
folic acid	Folic acid and	vitamin b12 and folic	B03BB01
	derivatives	acid	
			A11
	Vitamins	i.v. solution additives	B05XC

Table 11: Drugs for report 727310(continued)

Medicine Name	Medicine Class	Action	ATC Code
diclofenac	Other dermato- logicals	other dermatological preparations	D11AX18
diclofenac	Acetic acid derivatives and related substances	antiinflammatory and antirheumatic prod- ucts, non-steroids	M01AB05
diclofenac	Antiinflammatory preparations, non-steroids for topical use	topical products for joint and muscular pain	M02AA15
diclofenac	Antiinflammatory agents, non-steroids	antiinflammatory agents	S01BC03
prazosin	Alpha- adrenoreceptor antagonists	antiadrenergic agents, peripherally acting	C02CA01
amoxicillin	Penicillins with extended spectrum	beta-lactam antibacterials, penicillins	J01CA04
		vitamin b12 and folic acid	B03B
magnesium hydroxide	Magnesium compounds	antacids	A02AA04
magnesium hydroxide	Other urologicals	urologicals	G04BX01

Notes: New Delhi: The apex drug regulatory body, Central Drugs Standard Control Organization (CDSCO) has flagged 22 drug samples as 'Not of Standard Quality' after they failed to qualify a random drug sample test for the month of August. These drug samples included popular formulations and brands like Folic Acid Tablets I.P. 5mg, Diclofenac gel B.P. 1% w/w, Hypodermic Syringe 2ml, Herpivir-800 Tablets, RYAAL, Vibpure Hand Sanitizer, Ulcon Tablets, Allyn Instant Dry Hand Rub, Amzeclav-625 Tablets, and others.

This came after analysis and test conducted by the CDSCO, Drugs Control Departments, on 843 drug samples. Out of this, 821 samples were found of Standard quality while 22 of them were declared as Not of Standard Quality (NSQ). A few of the causes why the drug samples tested failed included Sterility, Assay, Dissolution, Description & Particulate Matter, Uniformity of weight, Assay of Isopropyl Alcohol, Assay of Ethyl Alcohol, and so on.

The samples were collected by the Drugs Control Department of Gujarat, Assam, Govt .of N.C.T of Delhi, Himachal Pradesh, and Srinagar Further CDSCO Ahmedabad, Ghaziabad, and Kolkata also picked up samples. Tests were conducted in three laboratories namely CDL Kolkata, RDTL Chandigarh, RDTL Guwahati. List of Drugs, Medical Devices and Cosmetics declared as Not of Standard Quality/Spurious/Adulterated/Misbranded, for the Month of August 2020

6 32% of herbal aphrodisiacs in north-western Nigeria contain Viagra Experts

Publication date 2020-09-23

Create date 2020-09-28

Score 6.32

Report id 739955

Category Herbal medicine, Erectile dysfunction medicine

Quality Diverted/Unregistered

Source Unknown

Curation Manually curated

Snippet: 32% of herbal aphrodisiacs in north-western Nigeria contain Viagra Experts NIGERIAN TRIBUNE

Click here to see the Original Article

Table 12: Places for report 739955

Region Name	Country	Location	Latitude	Longitude
Western Africa	Nigeria	Kano State	11.5	8.5
Western Africa	Nigeria	Kaduna State	10.33333	7.75
Western Africa	Nigeria	Zamfara State	12.16667	6.25
Western Africa	Nigeria	Katsina State	12.25	7.5

Table 13: Drugs for report 739955

Medicine Name	Medicine Class	Action	ATC Code
sildenafil	Drugs used in erectile dysfunction	urologicals	G04BE03

Notes: Experts have expressed concern that 32 per cent of herbal aphrodisiacs marketed across four north-western states in Nigeria were adulterated with sildenafil, a conventional drug used primarily to treat erectile dysfunction. [...] The experts had screened 50 herbal medicines preparations for enhanced sexual performance randomly collected across Katsina, Kano, Kaduna, Zamfara states for sildenafil and identified 16 of them containing between 0.45 and 39.8 mg of sildenafil per dose. They were collected from streets, herbal centres, local markets and stores. The 2020 study, in the Saudi Journal of Medical and Pharmaceutical Sciences, involved Aminu Lawal Tama at the Ahmadu Bello University, Zaria, Kaduna State in collaboration with Aminu

Musa, Musa A. Usman and Salisu Awwalu.

They stated that even at an extremely low dose of sildenafil, herbal-drug interaction or drug-drug interactions that are significant to health may also occur.

According to them, there is a need for an immediate intervention by relevant stakeholders to stop the consumption of these products which could have serious health risks to safeguard public health.

7 Wolverhampton Convenience Store Caught In Possession of Illegal Viagra-Like Pills and Cigarettes

Publication date 2020-09-29

Create date 2020-10-01

Score 5.64

Report id 746374

Category Erectile dysfunction medicine

Quality Diverted/Unregistered

Source Unlicensed outlets

Curation Manually curated

Snippet: Wolverhampton Convenience Store Caught In Possession of Illegal Viagra-Like Pills and Cigarettes Myhealthyclick

Click here to see the Original Article

Table 14: Places for report 746374

Region Name	Country	Location	Latitude	Longitude
Europe	United Kingdom	Wolverhampton	52.58547	-2.12296

Table 15: Drugs for report 746374

Medicine Name	Medicine Class	Action	ATC Code
sildenafil	Drugs used in erectile dysfunction	urologicals	G04BE03

Notes: A convenience store in Wolverhampton has been caught in possession of illegal cigarettes, tobacco, and Viagra-like drugs on several occasions. The store is to undergo a review of its premises license.

After several raids, Trading Standards bosses in Wolverhampton have called for a review in respect of Salvo's Convenience in Parkfield Road, Ettingshall, England.

The city's licensing bosses will discuss the review next week after the store was found to be selling suspected counterfeit tobacco products as well as a prescription drug advised for the treatment of erectile dysfunction (ED) despite not being a registered pharmacy.

[...] Slack revealed, "Seven Cildamax Sildenafil Citrate 100mg tablets, a pharmacy controlled drug used to treat erectile dysfunction were discovered behind the counter. In a van outside the shop, belonging to the manager, a further 1,160 packets of duty-free only' marked LIFA

menthol cigarettes and 329 Cildamax Sildenafil Citrate 100mg tablets were discovered."

8 Darknet Dealers are Selling COVID-19 Test Kits for Thousands of Dollars

Publication date 2020-09-11

Create date 2020-09-11

Score 5.62

Report id 723812

Category Medical device for screening/dia, Medical devices for disease prev, Vaccine, Anti-malarial

Quality Diverted/Unregistered

Source Website(s)

Curation Manually curated

Snippet: Darknet Dealers are Selling COVID-19 Test Kits for Thousands of Dollars VICE

Click here to see the Original Article

Table 16: Places for report 723812

Region Name	Country	Location	Latitude	Longitude
Americas	United States	United States	39.76	-98.5
		Earth	0	0

Table 17: Drugs for report 723812

Medicine Name	Medicine Class	Action	ATC Code
			J07
hydroxychloroquine	Aminoquinolines	antimalarials	P01BA02

Notes: VICE News spoke to one vendor who claims he's made more than \$1.4 million USD selling kits to hospitals and geriatric homes around the world. [...] Acting on a tip-off from connections in China and Hong Kong, the US-based businessman pulled together a network of like-minded entrepreneurs who bought thousands of COVID-19 IgM/IgG Rapid Tests directly from a handful of factories in Germany and Korea. [...] Speaking to VICE News over Wickr, Jason (not his real name) revealed that he's sold 8,000 COVID-19 testing kits on the dark web to dateeach one going for \$180 USD a piece. Half of those were snapped up by medical centres in Italy and the United States; 1,000 went to a geriatric home in an unspecified location; while another 3,000 were bought out by a single individual, who Jason suspects was acting on behalf of a mystery government or hospital. [...] Jason isn't the only illegal operator who's found a way to profiteer during the pandemic. VICE News found dozens of online dealers peddling

spurious coronavirus "vaccines", along with sheets of hydroxychloroquine pills and the blood of recovered COVID-19 patients for nearly \$16,000 USD per liter. [...] "Many of these vendors take advantage of the panic," he said. "There are some who promise to sell all kinds of remedies which are probably fake, [while] others sell protective gear like masks and hand santizers [amid] a worldwide shortage [and] we have strong reason to believe it's of low quality. We even know of some groups who sell used facemasks." [...] Any type of protective gear that hasn't been approved for use by the relevant authorities is not safe for use, says Maimon, who strongly advises against relying on any type of health-related commodity that has been acquired on the dark web.

"Of course there are a lot of fake drugs and commodities out there as well," he adds, "so consumers need to be vigilant regarding the manufacturers and the vendors they purchase from."

If Jason can be taken at his word, though, he's in the business of hoarding and selling coronavirus test kits for reasons that are more altruistic than financial suggesting that he's the one who doesn't have time for anyone not taking the COVID crisis seriously.

9 Buyers Fight CVS, Walgreens' Bid To Exit Blood Pressure MDL

Publication date 2020-09-21

Create date 2020-09-28

Score 5.23

Report id 736772

Category Cardiovascular medicine

Quality Substandard

Source Private pharmacy

Curation Manually curated

Snippet: Buyers Fight CVS, Walgreens' Bid To Exit Blood Pressure MDL Law360

Click here to see the Original Article

Table 18: Places for report 736772

Region Name	Country	Location	Latitude	Longitude
Americas	United States	New Jersey	40.16706	-74.49987

Table 19: Drugs for report 736772

Medicine Name	Medicine Class	Action	ATC Code
valsartan		angiotensin ii antago-	C09CA03
	tagonists, plain	nists, plain	

Notes: A class of consumers urged a New Jersey federal court to reject attempts by Walgreens, CVS and Rite Aid to escape multidistrict litigation alleging they misrepresented a generic high blood pressure drug, saying the pharmacies are shirking obligations by calling themselves drug testers instead of sellers. The consumers said Friday that the pharmacies' efforts to recast their duty as drug "pass through" centers instead of sellers "misses the mark." The drug buyers said the pharmacies failed to detect the sale of allegedly contaminated valsartan, a generic version of Diovan, which is primarily used to treat high blood pressure.

10 Public Notification: CHU Dietary Supplement Product contains hidden drug ingredients - 2020-09-09

Publication date 2020-09-09

Create date 2020-09-10

Score 5.15

Report id 722151

Category Nutritional supplement, Erectile dysfunction medicine

Quality Old News

Source Unknown

Curation Manually curated

Snippet: The Food and Drug Administration is advising consumers not to purchase or use CHU Dietary Supplement Product, a product promoted for sexual enhancement. This product was identified during an examination of international mail shipments.

Click here to see the Original Article

Table 20: Places for report 722151

Region Name	Country	Location	Latitude	Longitude
Americas	United States	United States	39.76	-98.5

Table 21: Drugs for report 722151

Medicine Name	Medicine Class	Action	ATC Code
tadalafil	Drugs used in erectile dysfunc- tion	urologicals	G04BE08
sildenafil	Drugs used in erectile dysfunc- tion	urologicals	G04BE03

Notes: [10-9-2019] The Food and Drug Administration is advising consumers not to purchase or use CHU Dietary Supplement Product, a product promoted for sexual enhancement. This product was identified during an examination of international mail shipments.

FDA laboratory analysis confirmed that CHU Dietary Supplement Product contains sildenafil and tadalafil, the active ingredients in the FDA-approved prescription drugs Viagra and Cialis, respectively, used to treat erectile dysfunction. These undeclared ingredients may interact with nitrates found in some prescription drugs, such as nitroglycerin, and may lower blood pressure

to dangerous levels. People with diabetes, high blood pressure, high cholesterol, or heart disease often take nitrates.

11 Liberia: LRA Customs Turns Over Counterfeit Medicines to LMHRA

Publication date 2020-09-01

Create date 2020-09-04

Score 4.42

Report id 711310

Category Vitamin, Antibiotic

Quality Diverted/Unregistered

Source Land point of entry

Curation Manually curated

Snippet: Liberia: LRA Customs Turns Over Counterfeit Medicines to LMHRA AllAfrica.com

Click here to see the Original Article

Table 22: Places for report 711310

Region Name	Country	Location	Latitude	Longitude
Western Africa	Liberia	Republic of Liberia	6.5	-9.5
Western Africa	Guinea	Guinea	10.83333	-10.66667

Notes: The Customs Department of The Liberia Revenue Authority (LRA) has turned over to the Liberia Medicines and Health Products Regulatory Authority (LMHRA) a huge consignment of pharmaceutical products illegally imported

The pharmaceutical products were intercepted by Customs Anti-Smuggling Officers along the Somalia Drive following a tip-off.

According to a Customs investigation report, the assorted pharmaceutical products were smuggled into country through the Guinea, Ganta Border. The report further stated that the assorted medicines were concealed in twelve (12) jomo size boxes under other goods being legally imported.

The assorted medicines include Pain killer, Multi Vitamin, Cold Caps, Amoxicillin among others and is valued at over Five Thousand United States Dollars (US\$5,000).

Presenting the seized medicines to the LMHRA, LRA Manager of Anti-Smuggling & Investigation Unit (ASIU), MasuFahnbulleh said the Authority will remain steadfast in ensuring effective border security and protection under its border management strategy.

He disclosed that the importer identified as AbdullaiKamara without permit imported and smuggled the assorted medicines into Liberia.

12 Trimotal tablet recalled for failing requirement for public use

Publication date 2020-09-18

Create date 2020-09-28

Score 4.27

Report id 734091

Category
Antibiotic

Quality Substandard

Source Manufacturer

Curation Manually curated

Snippet: Trimotal tablet recalled for failing requirement for public use sggpnews

Click here to see the Original Article

Table 23: Places for report 734091

Region Name	Country	Location	Latitude	Longitude
South-Eastern Asia	Viet Nam	Socialist Republic of Vietnam	16.16667	107.83333

Table 24: Drugs for report 734091

Medicine Name	Medicine Class	Action	ATC Code
amoxicillin	Penicillins with extended spec- trum	beta-lactam antibacterials, penicillins	J01CA04
sulbactam	Beta-lactamase inhibitors	beta-lactam antibacterials, penicillins	J01CG01

Notes: The Administration sent its dispatch to departments of health in cities and provinces and Minh Hai Pharmaceutical Company in the Mekong Delta Province of Ca Mau which manufactures the pill countrywide yesterday asking to recall the drug for failing quality requirement. Before, according to the National Institute of Drug Quality Control's report of test result for Trimoxtal table 500/250 containing Amoxicilin 500mg, Sulbactam 250mg with registered number VD-20158-13 in the batch number 0040518 and manufactured date May 8, 2018 and expired date May 8, 2021, the tablet failed requirements of Sulbactam natri. Therefore, the drug authority decided to remove the drug from pharmacy shelves nationwide. Tablet manufacturer, Minh Hai Pharmaceutical Company, was asked to work with distributors to recall the drug in

retail pharmacies. Moreover, it must send report of production and distribution of the tablet as well as probe the cause of quality failure and the quantity of the drug was distributed in market.

13 Beware of Fraudulent Coronavirus Tests, Vaccines and Treatments - 2020-09-09

Publication date 2020-09-09

Create date 2020-09-10

Score 3.73

Report id 722073

Category Medical devices for disease prev, Antiviral others, Vaccine

Quality Old News

Source Not applicable

Curation Manually curated

Snippet: There are currently no FDA-approved drugs, including vaccines, to treat or prevent COVID-19. Products that claim to cure, treat, or prevent COVID-19 haven't been evaluated by the FDA for safety and effectiveness; they might be dangerous to you and your family.

Click here to see the Original Article

Table 25: Places for report 722073

Region Name	Country	Location	Latitude	Longitude
Americas	United States	United States	39.76	-98.5

Table 26: Drugs for report 722073

Medicine Name	Medicine Class	Action	ATC Code
			J07
chloroquine	Aminoquinolines	antimalarials	P01BA01

Table 27: Other Stories

ID	Title	Link
760715	Beware of Fraudulent Coronavirus Tests, Vaccines and	Link
	Treatments - 2020-09-21	

Notes: Meanwhile, some people and companies are trying to profit from this pandemic by selling unproven and illegally marketed products that make false claims, such as being effective against the coronavirus.

These fraudulent products that claim to cure, treat, or prevent COVID-19 haven't been evalu-

ated by the FDA for safety and effectiveness and might be dangerous to you and your family. [...] The FDA has also seen unauthorized fraudulent test kits for COVID-19 being sold online. Currently, the only way to be tested for COVID-19 is to talk to your health care provider.

At this time, the FDA has not authorized any COVID-19 test to be completely used and processed at home. The FDA has authorized the first COVID-19 test for home collection of samples, but those samples are to be sent to a laboratory for processing and test reporting. [...] There Are No Vaccines or Medicines for COVID-19, Yet [...] Fraudulent COVID-19 products can come in many varieties, including dietary supplements and other foods, as well as products claiming to be tests, drugs, medical devices, or vaccines.

The FDA has been working with retailers to remove dozens of misleading products from store shelves and online. The agency will continue to monitor social media and online marketplaces promoting and selling fraudulent COVID-19 products.

Recently, the FDA and the Federal Trade Commission issued warning letters to seven companies for selling fraudulent COVID-19 products. The products cited include teas, essential oils, tinctures, and colloidal silver (see product photosExternal Link Disclaimer on Flickr).

2020-10-22 25

14 Husband and wife plead guilty to naturalization fraud and conspiring to illegally import and distribute male enhancement products and counterfeit goods from China

Publication date 2020-09-24

Create date 2020-09-28

Score 3.11

Report id 741030

Category Nutritional supplement

Quality Diverted/Unregistered

Source Not applicable

Curation Manually curated

Snippet: Husband and wife plead guilty to naturalization fraud and conspiring to illegally import and distribute male enhancement products and counterfeit goods from China Coosa Valley News

Click here to see the Original Article

Table 28: Places for report 741030

Region Name	Country	Location	Latitude	Longitude
Americas	United States	United States	39.76	-98.5
Europe	Italy	Rome	41.89193	12.51133

Table 29: Drugs for report 741030

Medicine Name	Medicine Class	Action	ATC Code
tadalafil	Drugs used in erectile dysfunc- tion	urologicals	G04BE08
sildenafil	Drugs used in erectile dysfunc- tion	urologicals	G04BE03

Table 30: Other Stories

ID	Title	Link
757248	Ga. Couple Plead Guilty: Illegally Imported Male Enhancement Products	Link

Table 30: Other Stories (continued)

ID	Title	Link
740865	Husband and Wife Plead Guilty to Naturalization	Link
	Fraud and Conspiring to Illegally Import and Dis-	
	tribute Male Enhancement Products and Counterfeit	
	Goods from China - 2020-09-24	
741134	U.S. Attorney: Dahlonega couple imported mis-	Link
	branded male-enhancement drugs from China	
740879	Georgia couple plead guilty to illegally importing male	Link
	enhancement drugs	
740922	Husband And Wife Plead Guilty To Conspiring To	Link
	Illegally Import And Distribute Male Enhancement	
	Products	
742066	Ga Couple Plead Guilty To Illegally Importing Male	Link
	Enhancement Products	
748729	Ga. Couple Plead Guilty: Illegally Imported Male	Link
	Enhancement Products	
740814	Husband, wife plead guilty in male enhancement prod-	Link
	uct scheme	
742386	Georgia couple imported erectile dysfunction drugs la-	Link
	beled as beauty products, feds say	

Notes: Irfanali Momin and Shiba I. Momin a/k/a Saguftabanu Momin, husband and wife, have each pleaded guilty in Rome to naturalization fraud, and conspiring to illegally import misbranded drug products from China, receive misbranded drugs that had moved in interstate commerce, and to trafficking of counterfeit goods.

"These defendants profited by taking a shortcutone that could have had devastating consequences for individuals who purchased these products," said U.S. Attorney Byung J. "BJay" Pak. "By illegally importing and distributing products containing drugs that can only be obtained in the United States with a prescription written by a licensed, medical professional, the Momins put profit over public safety." "The health and safety of American consumers are placed at risk when they are unknowingly exposed to undeclared active pharmaceutical ingredients in misbranded drugs that are falsely labeled as dietary supplements," said Special Agent in Charge Justin C. Fielder, FDA Office of Criminal Investigations Miami Field Office. "FDA remains committed to pursuing those who endanger the U.S. public health by importing and distributing fraudulent and potentially dangerous products." [...] In order to evade import restrictions, the Momins' China-based suppliers mislabeled the boxes containing the illegal pills to make it appear that the boxes contained items that can be legally imported into the U.S., such as beauty products, health products, and health supplies. The Momins admitted to selling between \$550,000 and \$1.5 million in illegal drug products over the course of the conspiracy. [...]

15 Alert Over Dangerous vet Medicine in Market Kenya News Agency

Publication date 2020-09-03

Create date 2020-09-07

Score 2.55

Report id 714108

Category Other, Veterinary medicines, Antibiotic

Quality Diverted/Unregistered

Source Unknown

Curation Manually curated

Snippet: Alert Over Dangerous vet Medicine in Market Kenya News Agency Kenya News Agency

Click here to see the Original Article

Table 31: Places for report 714108

Region Name	Country	Location	Latitude	Longitude
Eastern Africa	Kenya	Republic of Kenya	1	38

Table 32: Drugs for report 714108

Medicine Name	Medicine Class	Action	ATC Code
	Antibiotics	intestinal antiinfectives	A07AA
	Antibiotics	agents for treatment of	C05AB
		hemorrhoids and anal	
		fissures for topical use	
	Antibiotics	antifungals for topical	D01AA
		use	
	Antibiotics	antiinfectives and anti-	G01AA
		septics, excl. combi-	
		nations with corticos-	
		teroids	
	Antibiotics	antimycotics for sys-	J02AA
		temic use	
	Antibiotics	drugs for treatment of	J04AB
		tuberculosis	
	Antibiotics	throat preparations	R02AB
	Antibiotics	antiinfectives	S01AA

Notes: Animal health specialists have raised the red flag over manufacturers, importers and distributors who are taking advantage of wrangles at the Veterinary Medicine Directorate Board to flood the country with fake and poor quality drugs.

Animal Health Technicians and Technologists Association of Kenya (AHTTAK) said the situation was threatening Kenyans' health as foods of animal origin especially meat, milk eggs and honey were now registering harmful levels of drug residues especially antibiotics.

AHTTAK legal affairs Committee Chairman Oreste Karanja who spoke during a press conference in Nakuru today said due to absence of a regulator, veterinary drugs were now being sold and dispensed in open air markets, kiosks, groceries and hardware stores exposing Kenyans to health risks and economic losses. [...] "We are warning Kenyan farmers not to buy veterinary medicine from unauthorized outlets. In the current situation without a functional Veterinary Medicine Directorate quacks are having a field day while anyone can prepare a concoction and pass it off as a drug" she stated

She further said veterinary medicines being imported into the country were not being subjected to inspection at entry points to ascertain their safety and effectiveness as that was the preserve of the VMD.

Coordinator Calvin Ninga said recent studies have established that between 6 to 7 percent of milk samples collected on the markets around Nairobi had high levels of antibiotic residues.

Ninga said the situation was contributing to a growing antimicrobial resistance which he said was a creeping global public health catastrophe that needed urgent action.

16 Foothills Professional Pharmacy, LTD - 598883 - 09/09/2020 - 2020-09-29

Publication date 2020-09-29

Create date 2020-09-29

Score 2.00

Report id 746435

Category Other, Veterinary medicines, Antibiotic

Quality Substandard

Source Manufacturer

Curation Manually curated

Snippet: Compounding Pharmacy/Adulterated Drug Products

Click here to see the Original Article

Table 33: Places for report 746435

Region Name	Country	Location	Latitude	Longitude
Americas	United States	Phoenix	33.44838	-112.07404

Table 34: Drugs for report 746435

Medicine Name	Medicine Class	Action	ATC Code
tetracaine	Local anesthetics	agents for treatment of	C05AD02
		hemorrhoids and anal	
		fissures for topical use	
tetracaine	Anesthetics for	antiprurities, incl. anti-	D04AB06
	topical use	histamines, anesthetics,	
		etc.	
tetracaine	Esters of	anesthetics, local	N01BA03
	aminobenzoic		
	acid		
tetracaine	Local anesthetics	local anesthetics	S01HA03
lidocaine	Antiarrhythmics,	antiarrhythmics, class i	C01BB01
	class Ib	and iii	
lidocaine	Local anesthetics	agents for treatment of	C05AD01
		hemorrhoids and anal	
		fissures for topical use	

Table 34: Drugs for report 746435(continued)

Medicine Name	Medicine Class	Action	ATC Code
lidocaine	Anesthetics for topical use	antipruritics, incl. anti- histamines, anesthetics, etc.	D04AB01
lidocaine	Amides	anesthetics, local	N01BB02
lidocaine	Anesthetics, local	throat preparations	R02AD02
lidocaine	Local anesthetics	local anesthetics	S01HA07
lidocaine	Analgesics and anesthetics	other otologicals	S02DA01
benzocaine	Local anesthetics	agents for treatment of hemorrhoids and anal fissures for topical use	C05AD03
benzocaine	Anesthetics for topical use	antipruritics, incl. antihistamines, anesthetics, etc.	D04AB04
benzocaine	Esters of aminobenzoic acid	anesthetics, local	N01BA05
benzocaine	Anesthetics, local	throat preparations	R02AD01
phenylephrine	Adrenergic and dopaminergic agents	cardiac stimulants excl. cardiac glycosides	C01CA06
phenylephrine	Sympathomimetics plain	, decongestants and other nasal preparations for topical use	R01AA04
phenylephrine	Sympathomimetics combinations excl. corticosteroids	, decongestants and other nasal preparations for topical use	R01AB01
phenylephrine	Sympathomimetics	nasal decongestants for systemic use	R01BA03
phenylephrine	Sympathomimetics excl. antiglaucoma preparations	mydriatics and cyclo- plegics	S01FB01
phenylephrine	Sympathomimetics used as decongestants	decongestants and antiallergics	S01GA05

Notes: From July 9, 2018, to October 24, 2018, U.S. Food and Drug Administration (FDA) investigators inspected your facility, Foothills Professional Pharmacy, Ltd., located at 4545 E. Chandler Boulevard, Suite 100, Phoenix, Arizona 85048. During the inspection, the investigators noted that drug products you produced failed to meet the conditions of section 503A of the Federal Food, Drug, and Cosmetic Act (FDCA) [21 U.S.C. 353a] for exemption from certain provisions of the FDCA. In addition, the investigators noted serious deficiencies in your

practices for producing drug products, which put patients at risk.

FDA issued a Form FDA 483 to your firm on October 24, 2018 and issued an amended Form FDA 483 to your firm on December 20, 2018. FDA acknowledges receipt of your firm's response, dated November 14, 2018. Based on this inspection, it appears that you produced drug products that violate the FDCA.